Exhibit 24

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IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF NEW JERSEY

In re:	:	Chapter 11
	:	
LTL MANAGEMENT LLC,	:	Case No. 21-30589
	:	
Debtor.	:	
	:	

DECLARATION OF ANTHONY HERNANDEZ VALADEZ

Pursuant to 28 U.S.C. § 1746, I, Anthony Hernandez Valadez, declare under penalty of perjury as follows:

1. I am an adult over the age of 18 years and have personal knowledge of the facts expressed in this declaration. If asked, I could and would testify to the truth of such facts.

EXHIBIT 24

2. I am 23 years old and have been a lifelong resident of California.

3. In January 2022, I was diagnosed with mesothelioma. After subsequent scans, it is my understanding that my doctors have determined that I have pericardial mesothelioma.

4. I was born on September 23, 1998. When I was a baby, it is my understanding that my mother regularly used Johnson's Baby Powder talc on me, including during diaper changes and whenever it was needed. My mother and other family members continued using Johnson's Baby Powder talc on me throughout my childhood as part of my regular hygiene routine.

5. I first used Johnson's Baby Powder talc on myself when I was around 13 years old. I continued using that product for several years thereafter. During that time, I used a lot of Johnson's Baby Powder talc throughout my body, including on my chest, armpits, private areas, back, and neck. I used Johnson's Baby Powder talc every day, multiple times each day, including after showers, before going out, or whenever I need to freshen up. I applied that product either directly from the bottle or with my hands. It took me at least a couple of minutes to apply the powder. I used Johnson's Baby Powder talc because it was effective in combating sweat and odors. I also liked the product's fresh smell. Johnson & Johnson was a brand that I trusted. Using Johnson's Baby Powder talc generated visible dust that I breathed. I know that my family bought Johnson's Baby Powder at the following stores: Lucky, Safeway, Target, and Walmart.

6. Johnson & Johnson and the retailers from whom my family bought Johnson's Baby Powder never warned me or anyone else in my family about that product's asbestos content or asbestos-related health hazards, including cancer. If Johnson & Johnson and the retailers warned me or my family of such hazards, we would have never used Johnson's Baby Powder.

7. I do not recall any circumstance in which I or anyone in my household would have been in or around any dusty environments other than through my use of Johnson's Baby Powder. Before my diagnosis, I worked part-time as a customer service representative at Home Depot earning $15 per hour. At that job, I only helped customers buy doors and windows. I did not do any hands-on work with any tools, products, or any other machinery. Nor was I ever around any dusty environment. Prior to Home Depot, I was a customer service representative at Target and did no hands-on work with any tools, products, or any other machinery. For most of my life, my mother stayed at home to raise and care for me and my brother. Afterwards, my mom did yard duty and office work at a school. She currently works an office job at the local cemetery. My biological father died when I was four years old and I do not recall any interactions with him. My mother's current husband is a residential gardener who mows lawns and does landscaping. I never saw any dust on the work clothes of my mother or her current husband. I have never lived in or near any industrial areas or dust-generating facilities.

8. Prior to my mesothelioma diagnosis, I was an outgoing person who loved spending time with friends and family. For example, my friends and I often went out for dinner or lunch. I also enjoyed working and often worked overtime because of the camaraderie and several of my friends worked with me. I also enjoyed creative writing. Before my diagnosis, I was attending classes at Merced Community College and was only three semesters away from completing my Associates Degree. After obtaining that degree, I intended to transfer to a university in Southern California to major in criminology in the hopes of working in law enforcement or as a private investigator.

9. Having mesothelioma is the worst thing that has ever happened to me. I never had a serious, let alone life threatening, illness prior to my mesothelioma diagnosis. Mentally, this

illness has caused me great anxiety and depression. Talking about my current state makes my heart race to the point where I am having a panic attack. I refuse to communicate with any of my friends and family because I am in disbelief and shock that I am suffering from a terminal disease at such a young age. When I am in the hospital, I experience anxiety because I want to go home. When I am home, I experience anxiety because I fear that I will be back in the hospital. Physically, this disease and any treatments related to it, including two rounds chemotherapy, one round of immunotherapy, and cardiac surgery on February 17, 2022, have caused me to experience nausea/vomiting, loss of appetite, severe chest pain and tightness, shortness of breath, discomfort, fatigue, mouth sores, and chronic back pain.

10. I have either been seen in the emergency department or admitted several times since my diagnosis.

- **May 20-21, 2022:** I experienced shortness of breath and was admitted in the hospital.
- **May 19, 2022:** I was seen in the emergency department for shortness of breath. I was later discharged.
- **May 15-17, 2022:** On May 15, I was admitted in the hospital because of shortness of breath. Two days earlier, I received my first round of immunotherapy. During this stay, I was extremely anxious and wanted to leave because I was asked about topics related to my terminal illness. To help alleviate my anxiety, the doctor assured me that he will only talk about my symptoms. On May 17, the doctors assessed my PleurX catheters.
- **April 16, 2022:** I was seen in the emergency department because of my mouth sores. I developed these sores because of chemotherapy.
- **April 4 and 9-10, 2022:** I was seen in the emergency department because of complications related to my first round of chemotherapy.
- **March 28-April 1, 2022:** I was admitted because of continuing weakness and fatigue. I was so tired that merely walking from the house to the car causes me to breathe heavily and provokes other symptoms related to my mesothelioma

- **March 23-25, 2022:** I was admitted for nausea, vomiting, and low blood pressure. I experienced anxiety during this visit to the point where I threatened to leave despite the advice of my doctors.

11. I understand that this disease is terminal. No words can express my sadness in knowing that this disease has foreclosed me from the opportunity of realizing my hopes and dreams. As this disease progresses, my discomfort, anxiety, tiredness, and pain become more severe despite pain medication and treatment. I am very scared of what will happen to me.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief. I executed this Declaration at Palo Alto, California on May 21, 2022.

By: DocuSigned by: Anthony Hernandez Valadez D8C5883584094435
ANTHONY HERNANDEZ VALADEZ

Exhibit 25

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DECLARATION OF ANNA CAMACHO

Pursuant to 28 U.S.C. § 1746, I, Anna Camacho, declare under penalty of perjury as follows:

1. I am an adult over the age of 18 years and have personal knowledge of the facts expressed in this declaration. If asked, I could and would testify to the truth of such facts.

EXHIBIT 25

2. I am the mother of Anthony Hernandez Valadez ("Anthony"). He is the eldest of my two sons. Anthony suffers from and has been diagnosed with pericardial mesothelioma. It is my understanding that this disease is rare and terminal.

3. When Anthony was a baby, I regularly used a lot of Johnson's Baby Powder talc on him every day, multiple times each day, including during diaper changes, after baths, to treat or prevent diaper rash, and whenever it was needed. I packed the baby powder throughout Anthony's body, including on his private areas, arms, neck forehead, armpits, and chest. I applied the powder either directly from the bottle or with my hands. I also saw other family members apply Johnson's Baby Powder on Anthony while he was a baby.

4. Even after Anthony was no longer wearing diapers, I continued using Johnson's Baby Powder talc on him throughout his childhood. I applied that product in the same way and in the same areas that I previously mentioned in the paragraph above. Also, I applied Johnson's Baby Powder on Anthony's feet and in between his toes, as well as inside his shoes.

5. Anthony began using Johnson's Baby Powder talc on himself when he was around 13 years old and continued using it for several years afterwards. I know that Anthony was using Johnson's Baby Powder talc because the product was in the house and I saw remnants of baby powder on Anthony's clothes and armpits. I also reminded Anthony to use Johnson's Baby Powder because it was effective in combating odors and sweat.

6. Using Johnson's Baby Powder talc on Anthony always generated dust. Anthony breathed that dust.

7. I was the person in the household who bought Johnson's Baby Powder that was used on or by Anthony. The powder was in an all-white bottle. The twist cap was also white. The name "Johnson's" in script appeared on the front of the bottle. We always had multiple bottles of

Johnson's Baby Powder around the house. When Anthony was a baby, I always had a bottle of Johnson's Baby Powder in his diaper bag. I always bought the largest size of baby powder available. I also bought the travel size bottle. We used so much Johnson's Baby Powder that I bought it every two weeks from various retail and grocery stores, including Lucky, Safeway, Target, and Walmart. I have photographs that depict bottles of that product throughout the family home at various stages of Anthony's life. Johnson & Johnson's was a brand I trusted.

8. Johnson & Johnson and the retailers that sold its talc baby powder never warned me about the product's asbestos content or asbestos-related health hazards, including cancer. If Johnson & Johnson and the retailers warned me of such hazards, I would have never used Johnson's Baby Powder talc on me, Anthony, or his brother.

9. I do not recall any circumstance in which I or anyone in my household would have been in or around any dusty environments other than through my use of Johnson's Baby Powder. For most of Anthony's life, I was a stay-at-home mother who raised and cared for Anthony and his brother. It was not until 2007 did I start working again. In 2007, I did yard duty and office work at a school. I currently work an office job at the local cemetery. Anthony's father, Michael Valadez, died when Anthony was four years old. Michael did not work for pay because he was receiving aid from a federal assistance program for families with dependent children. Michael had no interaction with Anthony during Anthony's childhood. My current husband is a residential gardener who mows lawns and does landscaping. I never saw any dust on my, Michael's, or my current husband's work clothes. Anthony and I never lived in or near any industrial areas or dust-generating facilities.

10. I am in shock that Anthony has a terminal illness at such a young age. I care for Anthony every day and words cannot describe how his mesothelioma has negatively affected his mental and physical well-being. Anthony was outgoing and hardworking before his diagnosis. Now, he is suffering from anxiety and depression. He also experiences shortness of breath, extreme fatigue, lack of appetite, mouth sores, debilitating pain throughout his body, and other symptoms related to his pericardial mesothelioma. This disease has greatly traumatized me and Anthony. I highly doubt that we will ever recover from it.

11. Anthony and I live in Merced, California. Since his mesothelioma, Anthony has been admitted at or seen in the emergency department of Stanford Hospital in Palo Alto, California, for complications related to his mesothelioma. Each trip to and from Stanford Hospital takes close to two-and-a-half hours. These repeated and long trips to Stanford Hospital have caused Anthony extreme anxiety and depression. For example, during a recent

hospitalization during the week of May 16, 2022, Anthony was so distraught and anxious because his treating physician was discussing his terminal illness. The physician had to calm Anthony down and opted to only talk about Anthony's symptoms. Pasted herein is a picture I took of Anthony during that hospital stay.

12. As each day passes, Anthony's discomfort, pain, anxiety, fatigue, and other mesothelioma-related symptoms seem to worsen despite medications and treatment. He is unable to do even the most basic of tasks. I live in fear every day because I do not know whether Anthony will live to see another day.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief. I executed this Declaration at Palo Alto, California on May 21, 2022.

By: DocuSigned by: 3A27F890E614477...

ANNA CAMACHO

Exhibit 26

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Counsel for Movant Anthony M. Hernandez Valadez

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Debtor.	:	

DECLARATION OF WILLIAM E. LONGO, PH.D.

Pursuant to 28 U.S.C. § 1746, I, William E. Longo, Ph.D., declare under penalty of perjury as follows:

1. I have personal knowledge of the facts set forth in this Declaration, except for such facts that have been made known to me in forming an opinion, in which case each such fact is of

EXHIBIT 26

a type on which professionals in my field reasonably rely in forming such opinions. The facts stated in this Declaration that are within my personal knowledge are true. If asked, I could and would testify competently to the truth of and foundation for each fact and opinion asserted within this Declaration.

Background and Qualifications

2. Attached hereto as **Exhibit A** is a true and correct copy of my curriculum vitae, which truthfully sets forth my education, experience, and research on asbestos issues.

3. I have a Bachelor of Science degree in Microbiology, a Master of Science degree in Engineering, and a Doctorate in Philosophy in Materials Science, from the University of Florida.

4. I am currently employed at MAS, LLC ("MAS") as the Chief Executive Officer. For more than 30 years, I have studied the content, type, and release of asbestos fibers from asbestos-containing products, including products that contain talc. MAS is accredited by the American Industrial Hygiene Association for measurement of asbestos fibers by phase contrast microscopy. MAS is also certified by the International Standards Organization ("ISO") for measurement of bulk samples and air samples of asbestos. To date, MAS is the only laboratory in the country accredited by the American Association for Laboratory Accreditation A2LA, on behalf of ISO, for analysis of Asbestos in Cosmetic Talc Products by PLM (Blount prep method using heavy liquid separation: ISO 22262-1) and TEM (ISO 22262-2). MAS is also a registered FDA laboratory that is permitted to perform work for companies that want to submit MAS analysis for FDA approval.

5. As a materials scientist, I study the relationships among structures, properties, synthesis, and performance of a wide range of materials. I examine why and how materials behave under various conditions, such as temperature, pressure, stress or exposure to climatic conditions,

and how materials are used in every aspect of people's lives. I have spent the last 30 years studying all aspects of asbestos analysis including the use of air samples to analyze the airborne asbestos dust generated from the use of asbestos-containing products. This would include the use of both midget impinger and air cassettes. Under my direction our laboratory has analyzed approximately 400,000 asbestos bulk samples which does not include many thousands of air samples.

6. I have been qualified many times in courts throughout the United States as an expert witness in both material science and industrial hygiene matters relating to asbestos issues, including cases involving friction and talc powder products. For example, I have been qualified as an expert witness regarding my analysis of Johnson & Johnson talc products in more than 25 cases by courts across the country in 8 different states, including California courts in the counties of Alameda and Los Angeles.

7. I have published numerous articles on the subject of analysis and testing of asbestos-containing materials, including the quantification of asbestos particles released upon manipulation of these asbestos products in the manner performed in the work environment. My articles include: *Demonstration of the Capability of Asbestos Analysis by Transmission Electron Microscopy in the 1960's* in Microscope; *Asbestos Exposure During and Following Cable Installation in the Vicinity of Fireproofing* in Environmental Choices Technical Supplement; *Fiber Release During the Removal of Asbestos-Containing Gaskets: A Work Practice Simulation*, published in the Applied Occupational and Environmental Hygiene Journal in 2002; and *Zonolite Attic Insulation Exposure Studies*, in the International Journal of Occupational Health, published in 2010.

8. In February 2020, I and my co-authors published an article in the Journal of Occupational and Environmental Medicine reporting on 10 cases of serous ovarian cancer among

users of Johnson & Johnson cosmetic talc products. [Steffen, et al., *Serous Ovarian Cancer Caused by Exposure to Asbestos and Fibrous Talc in Cosmetic Talc Powders—A Case Series* (Feb. 2020) 62 J. Occup. Environ. Med. e65.] Talc was detected in all 10 tissue samples. As for those same samples, asbestos was detected in eight of them. The main types of asbestos identified in tissue, tremolite and anthophyllite, constitute a fingerprint for talc containing asbestos and indicate that the individuals in those cases were exposed to asbestos through their use of cosmetic talc powder. These cases provide more evidence of the causal link between asbestos, talc, and ovarian cancer. They also show that asbestos is present in consumer talc products at a level sufficient to cause disease. A true and correct copy of that article is attached hereto as **Exhibit B** and incorporated fully herein by reference.

9. On December 10, 2019, I was invited to testify for the U.S. Congressional Subcommittee on Economic and Consumer Policy entitled, "Examining Carcinogens in Talc and the Best Methods for Asbestos Detection," this testimony was about our use of heavy liquid separation for the detection of amphibole asbestos (tremolite and anthophyllite asbestos) using TEM for Johnson's Baby Powder. On February 4, 2020, I gave a presentation to the FDA's public meeting in Rockwell, Maryland entitled, "Testing Methods for Asbestos Detection in Talc & Cosmetics Products Containing Talc." For this presentation I discussed our use of heavy liquid separation sample preparation using both the Colorado School of Mines with ISO 22262-1 PLM analysis procedure for chrysotile detection, and the use of heavy liquid separation sample preparation with TEM analysis of amphibole asbestos in cosmetic talcs.

10. MAS has employees with expert knowledge in a broad range of fields including material sciences, organic and inorganic chemistry, physics, biology, microbiology, industrial hygiene, geology, and all types of microscopy. MAS has performed consulting work for

government agencies such as the Centers for Disease Control, National Institutes of Health, Federal Aviation Administration. MAS has also worked as an expert for the Cities of New York, Los Angles, San Francisco, Baltimore, Boston, and Chicago, the States of New York, Utah, Hawaii, and Texas in their respective asbestos products building litigations against former asbestos manufactures of surface treatment products (fireproofing, acoustical plasters etc.).

11. MAS's studies and video recorded demonstrations have been used for educational and training purposes in conjunction with the AIHA, American Society of Safety Engineers, the Environmental Institute, Asbestos Hazard Emergency Response Act certification training, and the U.S. Public Health Service.

12. MAS uses the NIOSH 7402 method for Transmission Electron Microscopy ("TEM") to determine whether fibers counted are asbestos versus non-asbestos. The TEM NIOSH 7402 method uses the direct preparation techniques. Such testing techniques are standardized in the scientific community.

13. It is a generally accepted scientific method to calculate the amount of fibers in the total volume based on the number of fibers found in the grid openings observed on the filter. Specifically, under proper counting TEM protocol, there are a specific number of grid openings that need to be analyzed to maintain the proper sensitivity in order to calculate the number of fibers per the entire volume. Because TEM protocol analyzes the samples based on a certain number of [1/1000 of a meter] grid openings, this is akin to 1-2% of the entire volume. The generally accepted TEM protocol dictates the number of grid openings that must be analyzed to have proper sensitivity as to the entire volume content, which our laboratory follows. [*See, e.g.*, 40 C.F.R. Appen. A, TEM Analytical Methods.]

Overview of MAS's Johnson & Johnson Testing

14. I have been qualified many times in courts throughout the United States as an expert witness in both material science, microscopy, and industrial hygiene matters relating to asbestos issues, including cases involving talcum powder products, including Johnson & Johnson products. My methodology in analyzing Johnson & Johnson talcum powder products for the presence of asbestos was subject to a *Daubert* hearing in the New Jersey MDL and has been found reliable. Moreover, I have been qualified as an expert witness regarding my analysis of cosmetic talcum powder products in more than 25 cases by courts across the country in 8 different states.

15. My laboratory, MAS, has now issued reports for the testing of approximately 146 containers of Johnson & Johnson talc products (primarily Johnson's Baby Powder) that cover a span of decades. This number will continue to increase as I obtain and test additional containers. Of the 146 containers, approximately 7 of them were purchased by MAS off-the-shelves of local drug stores and 67 of them were obtained were obtained from lawyers representing plaintiffs in lawsuits against Johnson & Johnson. Those 67 containers included Johnson & Johnson talc products purchased off the shelf or from the attorneys' clients themselves, while others came from collectors. The other 72 containers were obtained directly from the Johnson & Johnson archive.[1] The results of the initial 30 containers are contained in my report dated August 2, 2017 and later updated with additional containers in reports from March 2018, July 2018, February 2019, February 2020, March 2020, April 2020, December 8, 2020, January 25, 2021, February 9, 2021,

[1] Pursuant to the deposition testimony of Margaret Gurowitz on July 12, 2018 in *In Re: Johnson & Johnson Talcum Powder Products Marketing, Sales Practices, and Products Liability Litigation*, a true and correct copy of the cited excerpts are attached hereto as **Exhibit C**, Johnson & Johnson's corporate historian assembled the containers from the corporate archives museum at Johnson & Johnson. [Exh. C at 18:15-20, 25:19-26:22, 27:14-23, 28:13-29:2, 35:17-36:17.]

March 23, 2021, April 13, 2021, May 25, 2021, and June 4, 2021.[2] The results for the remaining 72 Johnson & Johnson archive containers are contained in my reports dated February 2018, November 2018, January 2019, February 2019, August 2019, and October 2019.

16. My lab has also analyzed 15 samples of Imerys Vermont talc produced from its archive. [January 15, 2019 report.] These Imerys samples represent Vermont milled talc ores that would have been shipped to Johnson & Johnson for use in its talcum powder products. Recently, my laboratory analyzed 29 talc and talc ore samples from the Guangxi Chinese talc mines used to manufacture Johnson & Johnson talcum powder products beginning in approximately 2003 (as well as various other talcum powder products). The 29 "Supra H" Guangxi Chinese talc samples were received by my laboratory from three sources: 2 samples from experts working for talc defendants in litigation (Segrave and Sanchez), collected by them directly from the Imerys mining and milling facility, 9 from Johnson & Johnson as retained by them in the regular course of their manufacturing Johnson's Baby Powder, and 18 from Chanel, Inc. as retained by them in the regular course of their manufacturing Chanel talcum powder products. The results of my laboratory's testing of the Supra H Guangxi Chinese talc are contained in my reports dated September 16, 2020 and October 8, 2020.

17. To date, we have identified and reported on regulated asbestos in 88 of 112 containers (79%) of Johnson's Baby Powder and Shower to Shower manufactured in the United States between the 1920s and 2019 (69/88 or 78% for Johnson's Baby Powder and 19/24 or 79% for Shower to Shower). Together with the Supra H Guangxi talc samples, and Johnson's Baby

[2] Three additional containers of Shower-to-Shower were received as part of the original non-Johnson & Johnson archive containers (M66510-001, M66511-001, M66512-001). Two belonging to individual plaintiffs in litigation and one was purchased new off the shelf from Walmart in 2017. Amphibole asbestos was found in two of the three containers by ATEM. No concentration preparation was used for the analysis of these containers at that time. These containers were manufactured by Valeant Pharmaceuticals and not Johnson & Johnson, and therefore not included in the above totals.

Powder samples manufactured with Chinese talc in the United Kingdom, to date, we have identified and reported on regulated asbestos in 77 of 81 Johnson & Johnson Chinese talcs and Chinese talc sourced products, or 95% (45/48 or 94%) Johnson's Baby Powder, 1/1 or 100% Johnson & Johnson Shower to Shower, 2/3 or 67% Valeant Shower to Shower, 29/29 or 100% Guang Xi Supra H Ore). We have further identified and reported on regulated asbestos in 116 of 146 containers of Johnson's Baby Powder and Shower to Shower, or 79% of the total amount of Johnson & Johnson talc products reported on to date. A true and correct copy of a summary chart of my laboratory's testing of Johnson & Johnson talc products, Imerys Vermont talc, and Supra H Guangxi Chinese talc is attached hereto as **Exhibit D**. I hereby adopt and incorporate that summary chart into this declaration as though it was set forth in full.[3]

18. For the reports on the samples received from the Johnson & Johnson archives, we expanded our initial testing to include XRD (x-ray diffraction),[4] PLM (polarized light microscopy), PLM with heavy liquid separation (Blount), in addition to the TEM we did in our initial reports. The methods utilized, ISO 22262-1 and 22262-2, are international methods generally accepted in the scientific community and, ISO 22262-2 is specifically tailored to the analysis of talc for asbestos. As with the initial reports, we analyzed both Johnson's Baby Powder and Shower-to-Shower talcum powder products. Our results are summarized in the table below:[5]

Method	# Containers Positive for Regulated Asbestos
TEM (ISO 22262-2 with concentration)	44 of 72 (61%)
Blount PLM (Heavy Liquid Separation)	41 of 72 (57%)
PLM (ISO 22262-1)	17 of 72 (24%)

[3] The reports my laboratory generated are voluminous. The pertinent data within those reports is reflected in the summary chart (Exhibit D). I hereby adopt and incorporate each of my reports analyzing Johnson & Johnson talc products into this declaration as though they were set forth in full. Copies of each of the reports will be furnished upon request.

[4] We worked together with Lee Poye of J3 Resources for the XRD analysis.

[5] (Exhibit D) Obviously, there was overlap on some of the positive samples between methods, where more than one method detected regulated asbestos. Two positive XRD samples were from Johnson's Baby Powder containers that used a tremolitic talc mine in Korea.

XRD (ISO 22263-3)	2 of 72 (3%)*
TOTAL	**52/72 or 72%**

19. Our initial results demonstrate a clear relationship between method and sensitivity. Use of the concentration preparation method with TEM and Blount/PLM were most sensitive, followed by standard PLM. XRD can only detect the presence of a mineral down to about 0.1% to 0.5% (depending on asbestos type). It is not surprising that XRD found only 2 out of 72 samples tested for amphibole minerals as they tended to occur at levels far below XRD's limit of sensitivity of 0.1% to 0.5% by weight. Also, we observed cleavage fragments but they were not counted.

20. Based on testing done on Supra H/Guangxi Chinese talc and talc-containing products by talc supplier Imerys and Andreas Saldivar under contract for the FDA, it appears that chrysotile is the mineral that is being found in this Chinese ore used by Johnson & Johnson and other companies manufacturing cosmetic talc products. As a result, following ISO 22262, my laboratory began investigating sample preparation techniques sensitive to identifying chrysotile in talc. In my review, I came across a heavy liquid separation ("HLS") sample preparation technique for PLM developed by Johnson & Johnson's consultant, Colorado School of Mines ("CSM") in 1973, specifically for the detection of chrysotile in talc.[6] My laboratory implemented the CSM PLM preparation technique in January 2020.

21. Initially, using the CSM preparation technique, we demonstrated that the use of HLS at a density of 2.70 g/cc can concentrate the chrysotile if present at a detection limit of 0.0001 wt. % or above by PLM. At that time, our reported weight percentages of chrysotile in cosmetic talc were overestimations caused by our use of the NIST 1886b chrysotile for the spiked weight

[6] Colorado School of Mines Research Institute Report Re: Mineralogical Examination of Five Talc Samples to W.H. Ashton from W.P. Reid and W.T. Caneer, February 26, 1973; Colorado School of Mines Research Institute Report Re: Mineralogical Examination of Four Samples for Tremolite and Chrysotile from W.P. Reid and W.H. Ashton, April 2, 1973

standards. The large size of chrysotile bundles from the NIST standard caused our PLM analysts to overestimate the visual volume weight estimation by approximately 2 to 3 orders of magnitude. As a result, we prepared spiked talc standards using Calidria chrysotile asbestos, a smaller milled product consistent with what is expected in cosmetic talcum powder. The Calidria standards (Union Carbide Calidria grade RG144) is a better match for the chrysotile detected in the cosmetic talcs we analyzed for two primary reasons: 1) the average bundle length and width of the Calidria standard is the same range as what we are detecting in the milled cosmetics talc, and 2) the refractive index (RI) ranges for the Calidria are in the range of the milled chrysotile in the talcum powder. The use of an appropriate standard comparison is required by the ISO 22262-1 PLM method.[7]

22. These modifications do not alter the ISO 22262-1 method for identifying and quantifying asbestos in a talc sample. These modifications relate solely to the CSM preparation technique and, as indicated above, ISO 22262-1 specifically allows for the use of preparation techniques the analyst deems appropriate for the sample being analyzed.[8] The modifications are also appropriate in that they serve as effective updates to a preparation technique developed 47 years ago in 1973. For example, we now measure lead levels in blood with inductively coupled plasma mass spectrometry, which permits great accuracy and precision. But they used to measure lead by a colorimetric method where the reagents used would produce different absorption for a positive sample. As another example, scientists used to use optic microscopes to count red blood cells. But today, red blood cells are counted automatically, most commonly with electronic impedance or laser light scattering (flow cytometry). Scientists build on the efforts of those who came before them.

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[7] ISO 22262-1 at 17-18.
[8] *Id.* at 14.

23. Even though the talc industry was aware from as early as 1973 that the heavy liquid separation PLM method increased the sensitivity for the detection of asbestos in talc, the talc industry, through its trade group CTFA, never incorporated concentration techniques for the routine analysis of talc and instead promulgated a substantially inferior method (J4-1) that did not require the use of an electron microscope and could only detect asbestos at levels above 0.5% by weight.

24. I have tested Johnson & Johnson products that encompass the eras of all three of sources for Johnson & Johnson talc products offered for sale in the United States (Italy, Vermont, China) as well as talc offered for sale in Asia, Australia, and the United Kingdom. As I have stated in the past, in the United States, we are dealing with three mining regions: the Italian region, the Vermont region, and the Chinese region. Our testing has shown regulated asbestos in containers sourced from each of these mines. Moreover, I have reviewed hundreds of Johnson & Johnson and Imerys internal documents demonstrating repeated and consistent instances of asbestos in each of these sources.

Airborne Concentrations – Shaker Powder Application

25. To determine the exposure an individual would have to airborne asbestos amphibole fiber during application of talc powder products, MAS conducted a below-the-waist application study using Johnson's Baby Powder talc container M65205-001.[9] Approximately four grams of Johnson's Baby Powder were applied to the lower body of an investigator to determine the potential exposure levels of an individual to asbestos amphibole fibers while

[9] Italy was the talc source for this container. Italian talc has been found to contain the highest concentration of tremolite asbestos. The highest concentration allows us to provide a "worst case scenario" exposure assessment. Due to the wide use of Italian talc in numerous talc powder products, including Johnson's Baby Powder, the data from this study is applicable to a variety of products containing Italian-sourced talc.

applying talc powder. Both the NIOSH 7400 PCM method and the NIOSH 7402 TEM method[10] were performed to determine if any detectable amphibole asbestos fibers from the Johnson's Baby Powder were released into the breathing zone of the investigator and immediate surrounding area. The NIOSH 7400 PCM analysis found that the four personal sample results ranged from 3.85 to 5.86 fibers per cubic centimeter ("f/cc"), with an average mean of 4.52 f/cc. Area air sample results were 0.28 f/cc to 0.58 f/cc with an average mean of 0.41 f/cc. Four of the personal PCM filters were analyzed by the NIOSH 7402 TEM method and the percent tremolite asbestos fiber concentration ranged from 42.9% to 76.9% resulting in a PCM equivalent range of 1.81 f/cc to 4.51 f/cc. A true and correct copy of MAS Project 14-1852 Below the Waist Application of Johnson & Johnson Baby Powder Supplemental Report #2 dated January 2018 is attached hereto as **Exhibit E** and incorporated fully herein by reference.

Anthony M. Hernandez Valadez

26. I have reviewed the declarations of Anthony M. Hernandez Valadez and his mother Anna Camacho, a true and correct copy of each is attached hereto as **Exhibits F and G**, respectively. I understand that Mr. Valadez is 23 years old and was diagnosed with pericardial mesothelioma. He had virtually lifelong, daily exposures to Johnson's Baby Powder talc. When Mr. Valadez was a baby, his mother regularly used a lot of Johnson's Baby Powder talc on him every day, multiple times each day, including during diaper changes, after baths, to treat or prevent diaper rash, and whenever it was needed. His mother packed the baby powder throughout his body, including on his private areas, arms, neck, forehead, armpits, and chest. She applied the powder either directly from the bottle or with her hands. His mother also saw other family members apply Johnson's Baby Powder on him while he was a baby. Even after

[10] These published NIOSH methods are accepted in the scientific community as reliable in determining airborne exposure levels to asbestos.

Mr. Valadez was no longer wearing diapers, his mother continued using Johnson's Baby Powder talc on him throughout his childhood. She applied that product in the same way and in the same areas as described above. In addition, his mother applied Johnson's Baby Powder on his feet and in between his toes, as well as inside his shoes. Mr. Valadez began using Johnson's Baby Powder talc on himself when he was around 13 years old and continued using it for several years thereafter. He used a lot of Johnson's Baby Powder talc throughout his body, including on his chest, armpits, private areas, back, and neck. His mother likewise knows that her son used Johnson's Baby Powder as a teenager because she saw remnants of baby powder on his clothes and armpits. Mr. Valadez used Johnson's Baby Powder talc every day, multiple times each day, including after showers, before going out, or whenever he need to freshen up. He applied that product either directly from the bottle or with his hands. It took at least a couple of minutes for him to apply the powder. Using Johnson's Baby Powder talc in the manner described above always generated visible dust, which he breathed.

27. Based on my review of the declarations of Mr. Valadez and Ms. Camacho, the manner in which they used Johnson's Baby Powder was similar to the application procedure that MAS followed for the Below-the-Waist exposure study and similar exposure scenarios that have found similar numbers. The results of the Below-the-Waist study and similar representative data show that an individual, such as Mr. Valadez, who used asbestos-containing Johnson's Baby Powder talc with a shaker application can have a significant exposure to airborne amphibole asbestos fibers. The magnitude of the asbestos fiber exposure levels will depend on the concentration level of the asbestos in the talc powder (e.g. as the concentration of asbestos in the product increases, the greater the concentration will be of the respirable airborne fibers). As a result, these findings of the release of asbestos during below-waist application are applicable to

any asbestos-containing talc powder product used in a substantially similar manner. These exposure levels substantially exceed background exposure levels reported in the literature.

28. Based on our own testing, as well as my review of historic testing of the talc ore used by Johnson & Johnson and historic testing of Johnson & Johnson finished talc products, it is my opinion to a reasonable degree of scientific certainty that individuals who used Johnson's Baby Powder, including Mr. Valadez, would have, more likely than not, been exposed to fibrous amphibole asbestos, especially with repeat purchases. Accordingly, it is my opinion that the asbestos exposure to individuals, like Mr. Valadez, who regularly and consistently used Johnson & Johnson Baby Powder for decades was substantial and well above background or ambient levels.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief. I executed this Declaration at Suwanee, Georgia on May 23th, 2022.

By: _____
WILLIAM E. LONGO, PH.D.

Exhibit A

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VITAE

William Edward Longo, Ph.D
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EDUCATION

October 1980 to December 1983	Received Doctor of Philosophy in Materials Science and Engineering, University of Florida
June 1979 to October 1980	Completed requirements for Master of Science in Materials Science and Engineering, University of Florida
September 1972 to June 1977	Received Bachelor of Science degree; Major in Microbiology, Minor in Chemistry, University of Florida.

PROFESSIONAL WORK HISTORY

February 2020 to Present	Chief Executive Officer
September 1987 to January, 2020	President of MAS, LLC (previously Materials Analytical Services, Inc.) Suwanee, Georgia.
August 1987 to February 1988	President and Founder of Longo Microanalytical Services, Inc., Gainesville, Florida.
October 1983 to August 1987	President and Founder of Micro Analytical Laboratories, Inc., Gainesville, Florida.
March 1985 to December 1987	Visiting Assistant Professor; University of Florida, Department of Materials Science and Engineering.
August 1983 to March 1985	Post Doctoral Associate; University of Florida, Department of Materials Science and Engineering.

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PATENTS

U. S. Patent Serial No. 4671954 June 9, 1987. Goldberg, E.P., Iwata, H., and Longo, W.E., "Microspheres for Incorporation of Therapeutic Substances and Methods of Preparation Thereof."

U. S. Patent Serial No. 4871716, October 3, 1989. Goldberg, E.P., Longo, W.E., and McCluskey, R.A., "Magnetically Responsive, Hydrophilic Microspheres for Incorporation of Therapeutic Substances and Methods of Preparation Thereof."

PUBLICATIONS AND PRESENTATIONS

February 4, 2020-FDA Presentation: Testing Methods for Asbestos in Talc & Cosmetic Products Containing Talc, Public Meeting, Rockville, Maryland.

Steffan, Joan, Tran, Triet, Yiman, Muna, Clancy, Kate, Bird, Tess, Rigler, Mark, Longo, William, Egilman, David, "Serous Ovarian Cancer Caused by Exposure to Asbestos and Fibrous Talc in Cosmetic Talc Powders, A Case Series, *JOEM-19-7875,* Vol. XX, Number X, 12/2019

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Egilman, David, Stefen, Joan, Tran, Triet, Clancy, Kate, Rigler, Mark, Longo, William "Health Effects of Censored Elongated Mineral Particles: A Critical Review, ASTM, STP 1618, 2019

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Rigler, M.W., Longo, W.E., "Qualitative Sulfur Gas Emission as a Specific Marker for Problematic Reactive Drywall, Proceedings of the Technical Symposium on Imported Corrosive Drywall, November 5-6, 2009, the University of Florida, Gainesville, FL.

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Longo, W.E., "The Identification of Asbestos Containing Surface Treatment Products using Standard Analytical Techniques" Florida Environmental and Asbestos Council Meeting, January, 1996.

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Longo, W.E., Rigler, M.W. and Slade, J., "Crocidolite Asbestos Fibers in Smoke from Original Kent Cigarettes" Cancer Research 55 11, 2232, 1995.

Longo, W.E., "Occupational Exposure From In-Place Asbestos Containing Fireproofing" Environmental Information Association, April, 1995.

Keyes, D. L., Ewing, W. M., Hays, S. M., Longo, W. E. and Millette, J.R., "Baseline Studies of Asbestos Exposure During Operations and Maintenance Activities" Appl. Occup. Environ. Hyg. 9(11) Nov, 1994.

Goldberg, E.P., Quigg, J., Sitren, H., Hoffmann, E., Jayakrishnan, A., Longo, W. and Cantrell, J., "Microsphere Drug Carriers for Targeted Chemo Immunotherapy and for Intracellular Infections" 20th Annual Meeting of the Society for Biomaterials, 1994.

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Ewing, W. M., Chesson, J., Dawson, T. A., Ewing, E. M., Hatfield, R. L., Hays, S. M., Keyes, D. L., Longo, W. E., Millette, J. R., and Spain, W. H. "Asbestos Exposure During and Following Cable Installation in the Vicinity of Fireproofing" Environmental Choices Technical Supplement, Volume I, (2), 1993.

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Keyes, D. L., Chessan, J., Hayes, S. M., Hatfield, R. L., Ewing, W. M., Longo, W. E. and Millette, J. R. "Re-Entrainment of Asbestos from Dust in a Building with Acoustical Plaster" Environmental Choice, Technical Support, Volume I, (6), 1992.

Longo, W. E. "A Standard Method for the Analysis of Asbestos in Settled Dust by TEM" Asbestos Measurement Risk Assessment and Laboratory Accreditation, ASTM Conference, July 1992. Johnson, Vermont.

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Hoffmann, E. M., Longo, W. E., and Goldberg, E. P. "Macrophage Uptake of Albumin Microsphere Drug Carriers" Proceedings of the 11th International Symposium on Controlled Release of Bioactive Materials, 11, 27, 1984.

Longo, W.E., "Albumin Microspheres for the Controlled Release of Therapeutic Agents" Doctor of Philosophy Dissertation, University of Florida, 1983.

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Longo, W. E., Iwata, H., Lindheimer, T., and Goldberg, E. P. "Preparation and Drug Release Properties of Albumin-Polyglutamic Acid-Adriamycin Microspheres" American Chemical Society, 24, 56, 1983.

Longo, W. E., Iwata, H., Lindheimer, T., and Goldberg, E. P. "Preparation of Hydrophilic Albumin Microspheres Using Polymeric Dispersing Agents" *J. Pharm. Sci.*, 71, 1323, 1982.

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Longo, W. E., Iwata, H., and Goldberg, E. P. "Hydrophilic Albumin-Polyglutamic Acid-Adriamycin Microspheres for Localized Chemotherapy" 8th Annual Meeting of the Society of Biomaterials, 10, 60, 1982.

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ACTIVITIES AND ORGANIZATIONS

* Member of Environmental Protection Agency Workshop on Sampling and Analysis of Asbestos in Settled Dusts, July 1989.

* Member of Environmental Protection Agency Peer Review Group for the Asbestos Engineering Program, 1987 to present.

* Vice-Chairman of the National Asbestos Council Analytical Subcommittee on Transmission Electron Microscopy 1987-1988.

* Chairman of National Asbestos Council Analytical Subcommittee on Transmission Electron Microscopy 1988-1989.

* Member of ASTM D-22-05 Subcommittee for Indoor Air Pollution.

LECTURES AND COURSES INSTRUCTED

Longo, W.E. "Electron Microscopy for Industrial Hygiene Applications" American Industrial Hygiene Conference Professional Development Course, Atlanta GA, May 2004.

Longo, W. E. "Settled Dust: Asbestos and Other Particulates"
Georgia Institute of Technology Seminar, August 1991.

Longo, W. E. "The Role of the Laboratory Manager, Quality Assurance Officer and the Analyst for NIST Accreditation" Georgia Institute of Technology, Transmission Electron Microscopy Asbestos Accreditation Seminar, August 1989.

Longo, W. E. 24th Annual Meeting of the Microbeam Analysis Society,
"Asbestos Analysis Session" Ashville, North Carolina, July 1989 (Session Co-Chairman).

Longo, W. E. "Fundamentals of Asbestos Analysis by TEM" Institute in Materials Science State University of New York. New Paltz, New York, October 1988 (Course Director).

Longo, W. E. "TEM Imaging/Photography" Georgia Institute of Technology, Transmission Electron Microscopy Asbestos Analysis Course, June 1988.

Longo, W. E. "Laboratory Preparation of Polycarbonate Filters for TEM Analysis"
Georgia Institute of Technology, Advanced Transmission Electron Microscopy Asbestos Analysis Course, February 1988.

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Longo, W. E. "Transmission Electron Microscopy Laboratory Set-Up" Georgia Institute of Technology, Advanced Transmission Electron Microscopy Asbestos Analysis Course, February 1988.

Longo, W. E. "Laboratory Analysis of Asbestos" Hall-Kimbrell Seminar in Asbestos Abatement in the State of Florida, January 1988.

Longo, W. E. "Air Sample Preparation and Analysis by TEM" Georgia Institute of Technology, Clearance Testing for Asbestos: AHERA Regulations, October 1987.

Longo, W. E. "Asbestos Air Sample Analysis by Transmission Electron Microscopy" American Industrial Hygiene Conference Professional Development Course, Montreal, Canada, May 1987.

Longo, W.E. "Asbestos Air Sample Analysis by Transmission Electron Microscopy" American Industrial Hygiene Conference Professional Development Course, Dallas, TX May 1986.

PROFESSIONAL MEMBERSHIPS

American Industrial Hygiene Association	1985, 1999 to Present
American Society for the Testing of Materials	1986 to Present
American Society of Materials	1994, 2009-Present
National Asbestos Council	1984 to 1993
Environmental Information Association	1993, 2008-Present
Materials Research Society	1988, 2010-2014
Electron Microscopy Society Association	1988 to Present
Micro Analysis Society formerly known as Microbeam Society	1988, 2009-2012, 2018
New York Academy of Science	1985 to 1987 1989 to 1994
Air Pollution Control Association	1985 to 1987

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National Institute of Building Sciences	1991 to Present
The Society for Ultrastructural Pathology	1996
American Society of Heating, Refrigerating and Air-Conditioning Engineers	1996 to Present
The American College of Forensic Examiners – Fellow of Forensic Engineering Technology (IN. 17825)	1999 to 2017
American Conference of Governmental Industrial Hygienist (ACGIH) Associate Member	2006 to Present, 2007-2009
American Chemical Society	2012-Present

Exhibit B

OPEN

Serous Ovarian Cancer Caused by Exposure to Asbestos and Fibrous Talc in Cosmetic Talc Powders—A Case Series

Joan E. Steffen, BA, Triet Tran, BA, BS, Muna Yimam, BS, Kate M. Clancy, Tess B. Bird, DPhil, Mark Rigler, PhD, William Longo, PhD, and David S. Egilman, MD, MPH

Objective: Asbestos is a known cause of ovarian cancer. We report 10 cases of serous ovarian cancer among users of Johnson & Johnson (J&J) asbestos-containing ''cosmetic'' talc products. **Methods:** We conducted an asbestos exposure assessment during talc application and analyzed surgical tissues and talc containers for asbestos and talc. **Results:** Talc was found in all cases and tremolite and/or anthophyllite asbestos was found in 8/10 cases. The asbestos fibers found in the ''cosmetic'' talc containers matched those found in tissues. We estimated inhaled asbestos dose ranged from 0.38 to 5.18 fiber years. **Conclusion:** We provide evidence that the inhaled dose of asbestos/fibrous talc from ''cosmetic'' talc use causes ovarian cancer. The unique combination of the types of asbestiform minerals detected in cancerous tissue and ''cosmetic'' talc is a fingerprint for exposure to asbestos-containing talc.

Keywords: asbestos, baby powder, cosmetics, Johnson & Johnson, ovarian cancer, talc

Known amongst oncologists as a ''silent killer,'' ovarian cancer is the leading cause of death from all gynecologic cancers and the fifth leading cause of cancer-related deaths among women in the United States.[1] The American Cancer Society estimates that about 22,000 American women will be diagnosed and 13,850 will die of the disease in 2019.[2] In 2010, the agency determined that perineal talc powder use is possibly carcinogenic to humans (group 2b).[3]

Epidemiological studies have examined the relationship between perineal talc use and ovarian cancer. In a 1982 case–control study, Cramer et al[4] first reported an association between genital talc use and ovarian cancer. At least 32 subsequent epidemiologic studies have examined the association between talc powder use and ovarian cancer.[5–36] High-grade serous carcinoma (HGSC) is the most common form of ovarian cancer and the type of ovarian cancer that has been most consistently associated with perineal use of cosmetic talc products.[6–8,10,12,14,15,24,27,29,32,33,36,37] Meta-analyses have consistently shown an increased risk of HGSC of about 1.3 for perineal talc use.[18,38–40]

Asbestos exposure by inhalation occurs during cosmetic talc use.[41,42] International Agency for Research on Cancer (IARC) concluded in 2009 that asbestos was a group 1 ovarian carcinogen.[43,44] Dr Wyers' first reported a case of ovarian cancer in a woman with asbestosis in 1949.[45] Twenty-seven epidemiologic studies have since examined the relationship between asbestos exposure and ovarian cancer.[46–72] Nine of these 27 studies report a statistically significant elevation in ovarian cancer risk.[46–48,51,61,62,68,69,71] Epidemiologic findings have demonstrated consistency in different populations: studies of asbestos and ovarian cancer have shown a statistically-significant association among women in different countries with exposures to different types of asbestos fibers and in various occupational and environmental settings.[46–48,51,61,62,68,69,71] Epidemiologic research also suggests a dose–response relationship for asbestos and ovarian cancer when comparing low-exposure and high-exposure subgroups.[47,72] Camargo et al[73] performed a meta-analysis of 18 cohort studies of occupational asbestos exposure and reported a pooled standardized mortality ratio (SMR) for ovarian cancer of 1.77 (95% confidence interval [CI], 1.37–2.28).

Epidemiologic studies of talc and ovarian cancer have generally accepted representations by talc mining and manufacturing companies that consumer talc has been asbestos-free since 1976.[6–8,10,12,14,15,24,25,27,29,32,36] However, studies show that

From the Never Again Consulting, Attleboro, Massachusetts (Ms Steffen, Mr Tran, Ms Yimam, Ms Clancy, Dr Bird, Dr Egilman); College of Engineering and Mines (student), University of Alaska – Fairbanks, Fairbanks, Alaska (Ms Clancy); Mellon Postdoctoral Fellow, Wesleyan University, Middletown, Connecticut (Dr Bird); Materials Analytical Services LLC, Suwanee, Georgia (Dr Rigler, Dr Longo); Department of Family Medicine, Warren Alpert Medical School, Brown University, Providence, Rhode Island (Dr Egilman).

Funding: Plaintiffs' attorneys in litigation against Johnson & Johnson (Ingham et al vs Johnson & Johnson et al) paid for tissue analysis for talc and asbestos in patient tissues. They also paid for travel costs and time spent examining and interviewing patients. There was no outside funding for work on this manuscript.

Institution and Ethics approval and informed consent: There was no requirement for ethics review or institutional review board approval because this research was not experimental and was originally conducted pursuant to a lawsuit. Informed consent was obtained from all living patients. For one deceased patient (Case No. 8), consent was obtained from the surviving spouse. For the remaining two deceased patients (Case No. 4 and Case No. 9), authors relied only on public information revealed during court proceedings.

Disclosure (Authors): T.T., J.S., K.C., M.Y. and T.B. work for Dr Egilman, who served as an expert witness in litigation at the request of people who were injured as the result of using talcum powders. Mr Tran, Ms Steffen, Ms Clancy, Ms Yimam, and Dr Bird were not compensated by law firms for work on this paper and the lawyers for the injured plaintiffs did not review this paper and had no input into the content of the paper.

Dr Egilman, Dr Rigler and Dr Longo report payments from lawyers related to the submitted work. All serve as expert witnesses in litigation at the request of people who were injured as the result of using talcum powders; plaintiffs' lawyers paid for the patient examinations taken by Dr Egilman as part of his expert witness work.

Dr Rigler and Dr Longo originally performed the tissue analysis for talc and asbestos as part of their expert witness work and were paid by plaintiffs' lawyers for their work. Dr Egilman has also served as an expert witness at the request of companies who have been sued for exposure to asbestos from their mines or products. They were not compensated for work on this paper and the lawyers for the injured plaintiffs did not review this paper and had no input into the content of the article.

Disclaimer: Historic testing of talc for asbestos is limited in methodology and scope. Courts and plaintiff lawyers have agreed, without the knowledge or permission of their clients, to keep secret some of the documents reported here; these documents became public during court proceedings over the objections of J&J and Imerys. Many documents remain sealed.

Supplemental digital contents are available for this article. Direct URL citation appears in the printed text and is provided in the HTML and PDF versions of this article on the journal's Web site (www.joem.org).

Clinical significance: We provide evidence that asbestiform minerals present in ''cosmetic'' talc causes ovarian cancer. We provide an estimate of asbestiform minerals inhaled per talc application and cumulative lifetime exposure. The unique combination of asbestiform minerals detected in cancerous tissue and ''cosmetic'' talc is a fingerprint for exposure to asbestos-containing talc.

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DOI: 10.1097/JOM.0000000000001800

consumer talc contains asbestos and a review of the world's largest talc producers records indicated that talc mines contained asbestos, that asbestos cannot be removed from talc, and that talc used in cosmetics was not asbestos-free.[41,74–82] Case control and cohort studies of talc use and ovarian cancer have not differentiated inhalation and perineal talc exposures, and have not considered inhalation exposures in their analyses; this has contributed to misclassification of exposed cases and inaccurate dose–response assessments.[42] In addition, industry marketing studies from the 1970s indicate that up to 85% of women used talc powders thus many ''controls'' were probably exposed to asbestos containing talcs.[42,83]

We report 10 cases of serous ovarian cancer among users of asbestos-containing Johnson & Johnson (J&J) cosmetic talc products. Unlike most previous studies on talc and ovarian cancer, we focused on inhalation exposures to asbestos during various talc uses and not perineal exposure.[4,6,12,40] We measured inhalation exposures during perineal application of asbestos-containing cosmetic talc. Based on exposure histories, we estimate the dose of inhaled asbestos and the increase in ovarian cancer risk for each case. Our case series also includes tissue analysis for talc and asbestos in both product and cancer tissue. By synthesizing current knowledge of asbestos carcinogenicity and evidence of asbestos in consumer talc products, our case series provides novel insight into the link between cosmetic talc use and ovarian cancer.

MATERIALS AND METHODS

We report 10 cases of serous ovarian cancer in women who primarily or exclusively used a variety of J&J cosmetic talc products including Johnson's Baby Powder (JBP), Shower to Shower (STS), and STS Shimmer.[84] These cases were identified among a group of 22 plaintiffs in Ingham et al versus Johnson & Johnson et al. All plaintiffs were diagnosed with ovarian cancer after exposure to J&J cosmetic talc products and transmission electron microscope (TEM) tissue analysis for talc and asbestos was performed for 10 of these plaintiffs. We only report on the 10 plaintiffs for whom TEM tissue analysis was completed.

There was no requirement for ethics review or institutional review board approval because this research was not experimental and patients participated voluntarily in conjunction with a lawsuit. Informed consent for publication was obtained from all living patients. One patient (Case No. 8) passed away after her exposure history was collected but before consent for publication was obtained. In this case, consent was obtained from the surviving spouse. For the remaining two deceased patients (Case No. 4 and Case No. 9), authors relied only on public information revealed during court proceedings. For the exposure assessment, the researcher wore a respirator and was decontaminated post-assessment. The researcher was not exposed to any risk, required to reveal personal information or subjected to specimen collection. The assessment did not meet the requirements to necessitate Institutional Review Board (IRB) approval.[85]

Patient Histories

Medical histories, exposure histories (history questionnaire attached as Appendix 1, http://links.lww.com/JOM/A685), and physical examinations were collected for all living patients (8/10 cases). Exposure histories included questions about talc powder use and other sources of asbestos exposure. We analyzed the frequency and duration of talc uses for each case. For the two deceased patients (Case No. 4 and Case No. 9), a rough exposure history was compiled from the testimony of relatives who were familiar with each patient. Available medical records were also reviewed for all cases.

Exposure Assessment—Perineal Application

The exposure assessment was completed in a $15'' \times 15'' \times 8''$ room with appropriate negative asbestos airflow technology. The experiment was videotaped using two Sony Model HDR-CX900 cameras with alternating Tyndall and standard lighting. (See Appendix 2, http://links.lww.com/JOM/A686.) Area and background samples were collected using four high-volume area sampling pump stations set up 5″ to 6″ from the talc user; these pump stations used 25 mm air cassettes containing 0.8 μm pore size mixed cellulose ester (MCE) filters with 5.0 μm backing pads and were calibrated to run at 10 L/min. Personal samples were collected using four low-volume pumps affixed to the talc user with the cassettes adjusted to be in the breathing zone of the investigator; the ''personal'' pumps were calibrated to 2.5 L/min. During the experiment, air samples were collected for 5 minutes from all sources.

A researcher wearing personal protective equipment and ''personal'' air pumps used a metal container of JBP for the experiment. Based on JBP advertisements featuring product images, we estimated that the JBP used in this test had been manufactured sometime in the 1950s and sourced from the Val Chisone mine.[86,87] (See Appendix 3, http://links.lww.com/JOM/A688 for images of JBP product tested and for full written report on exposure assessment.) J&J used this mine source from 1946 until 1968 and 1980 to 1981.[86–88] From 1969 to 2003, J&J used Vermont talc in their powder products and later switched to Chinese talc.[42,89] Using *t* test analysis, the asbestos content (fibers per gram) in all the bottles tested were statistically comparable across these three talc sources. (See Appendix 4, http://links.lww.com/JOM/A689)

The JBP can was weighed before the experiment using a Fisher Scientific balance. The researcher wore a bikini bottom over an inner pair of boxer briefs and sat on a chair in the middle of the room for the experiment. To simulate perineal talc application, the researcher shook the talc powder into his hand twice and then rubber the powder into the upper leg area. This was repeated for the other leg. Then, the researcher stood, pulled the bikini bottom down and away from the body, and applied two squeezes of talc powder into the bikini bottom. The researcher released the briefs and sat down on the chair for the remainder of the study. The metal container of JBP was weighed again following the study. After the study, two field blanks were opened inside the study room.

A total of four background samples, four personal samples, and four area samples were collected along with two field blanks. All 12 air samples were analyzed for asbestos by the National Institute Occupational Safety and Health (NIOSH) 7400 phase contrast microscopy method using ''A'' counting rules and by the NIOSH 7402 TEM method.[90,91] For TEM analysis, amphibole asbestos fibers or bundles with substantially parallel sides and an aspect ratio of 3:1 or greater, at least longer than 5.0 μm in length and greater than 0.25 μm were counted as per NIOSH 7402 asbestos structure sizing rules.[91] The four personal air samples were also analyzed by the NIOSH 7402 method for fibrous talc particles.[91] The two field blanks were analyzed for asbestos by phase contrast microscopy and TEM in accordance with NIOSH 7400 and NIOSH 7402.[90,91]

Dose Calculations

For each case, we calculated asbestos dose in environmental fiber years (for consistency with the Environmental Protection Agency (EPA) risk assessment model) and in total fibers inhaled (to account for changes in respiratory intake in infancy vs. adulthood).[92] We used the asbestos dose in environmental fiber years to calculate the excess risk. (See section on Dose–Response Risk Assessment.)

We calculated total asbestos dose based on the four most common usages of J&J talc powder reported among the 10 cases: perineal application (10/10), upper body powdering (9/10), exposure as an adult during diapering (8/10), and exposures as an infant during diapering (7/10). For each of these scenarios, we incorporated the intensity of the exposure (f/cc), duration of each exposure (minutes), and total number of applications (from exposure

histories) to calculate the dose. Although we did not adjust for latency, we excluded exposures that occurred after ovarian cancer diagnosis. Fibrous talc exposures from powdering were excluded from our calculations except exposure from baby diapering.[41] Dement et al[93] did not differentiate type of fiber detected.

For perineal powdering exposures, we relied on measurements from our exposure assessment. (See above.) Air samples were collected over the course of 5 minutes in this test.

For upper body powdering, we used Gordon's et al[41] measurements for shaker application of cosmetic talc powder to the underarm, shoulder, and upper arm area. Gordon et al[41] used Cashmere Bouquet, which used the same Italian mine source as J&J (Val Chisone) from 1940 until 1992.[94,95] Gordon et al[41] found that users were exposed to 1.9 f/cc of asbestos fibers over the course of 5 minutes.[41]

For exposures during diapering, Dement et al[93] from NIOSH found that an adult is exposed to 2.2 f/cc of fibrous material and that a baby is exposed to 1.8 f/cc over the course of two minutes. When subjects reported that their parents had used talc on them during diaper changes as an infant, we relied on diaper changing norms to estimate infant exposures. United States market research and survey data show that diaper changes typically occur 8 to 10 times per day for infants (0 to 6 months) and 4 to 6 times per day for toddlers (6 to 24 months).[96–98] Diaper changing frequency in the U.S. also changed over time: the average number of diaper changes per day over the first two years of life dropped from eight times per day in the 1960s to 5 to 6 times per day by the 1980s due to improvements in disposable diapers and reduction in cloth diaper use.[97,99] Since all of the women in our series were born prior to 1975, we assumed that diaper changes occurred eight times per day for two years.

We calculated the dose for each case in fiber years $\left(\frac{f}{cc} \times year\right)$ using the same conversions as Anderson et al.[100] For consistency with the EPA dose–response curve used for our risk assessment, we calculated the total duration of exposure based on a continuous, 24-hour exposure period (525,600 min/yr) until date of diagnosis.[92]

Formula 1:

Formula to estimate inhalation exposure from talc application:

$$\text{Asbestos exposure in } \frac{f}{cc} \times \frac{\text{duration of each exposure} \times \text{total number of applications}}{525,600 \text{ min per year}} = \text{total dose in } \frac{f}{cc} \cdot \text{years}$$

We also calculated the total number of asbestos fibers inhaled in each case. For adults, we used the National Research Council (NRC)'s estimate of "an annual inhaled air volume of 7,300 m^3" and formula to convert the dose from fiber years to total fibers.[101] We relied on measurements of infant lung volume from Hall[102] and on median infant respiratory rates calculated by Fleming et al[103] to estimate the total inhaled air volume for infants from age 0 to 2. Using time-weighted averages for tidal volume and respiratory rate, we calculated that infants breathed 11,025,072,000 ccs in the first 2 years of life, or 5,512,536,000 ccs per year on average.

Formula 2:

Formula to convert adult exposures to total fibers based on NRC (1984):

$$\left[\text{total does in } \frac{f}{cc} \times \text{years}\right] \times \frac{7,300,000,000 \ cc}{\text{year}} = \text{Total number of asbestos fibers}$$

Formula 3:

Formula to convert infant exposures to total fibers based on Hall[102] and Fleming et al[103]:

$$\left[\text{total does in } \frac{f}{cc} \times \text{years}\right] \times \frac{5,512,536,000 \ cc}{\text{year}} = \text{Total number of asbestos fibers}$$

We added together adult and infant exposures to calculate the exposures in total number of asbestos fibers. See Appendix 5, http://links.lww.com/JOM/A690 for the full dose calculations for each case.

Dose–Response Risk Assessment

We developed a method to apply the EPA dose–response curves for inhaled asbestos and mesothelioma risk to ovarian cancer risk.[92] First, we examined the EPA dose–response table for mesothelioma from environmental asbestos exposure (24-hours, 365 days per year).[92] Utilizing the EPA dose–response estimates, we extrapolated a formula for the line of best fit for mesothelioma risk.

We then identified studies that reported mesothelioma and ovarian cancer rates in the same cohort and calculated comparative risk of mesothelioma versus ovarian cancer for each study.[58,62,63,68,71] (See Table 1.)

Using these studies, we calculated the geometric mean comparative risk of contracting mesothelioma versus ovarian cancer from the same asbestos exposures. We applied this comparative risk to the line of best fit for mesothelioma based on the EPA dose–response data to determine a formula for risk of ovarian cancer.

The subjects of the EPA occupational exposure study were entirely men.[92] Since women are more susceptible to cancer from asbestos exposure, we used Lacourt's[104] findings comparing the mesothelioma odds ratio (OR) in men versus women with the same exposures to adjust the formula for the increase in cancer risk for women. At total doses more than 0 to 0.1 fiber years, women were 1.725 times more likely to have mesothelioma than men.[104] At total doses more than 0.1 to 1 fiber years, women were 2.855 times more likely to have mesothelioma than men.[104] We applied these ratios to the EPA dose curve calculated to obtain a better estimate of the ovarian cancer dose–response in women.

The resulting dose–response curve for inhaled asbestos and ovarian cancer is shown in Fig. 1. We used each case's asbestos dose estimate in fiber years to identify their relative lifetime risk of developing ovarian cancer along the dose–response curve. We then compared each case's risk of contracting ovarian cancer due to inhaled asbestos exposure to the expected incidence of ovarian cancer for those without asbestos exposure: 11.4 per 100,000 from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) Program.[105]

Tissue Analysis for Asbestos and Talc

Samples from a combination of the left and right ovaries, left and right fallopian tubes, and left and right pelvic lymph nodes were obtained from the hospital for each of the 10 patients. Tissues were analyzed to identify and quantify talc and asbestos content in the tissue.

For tissue analysis, a small portion of the tissue in each block was removed with a clean razor blade and placed in a pre-weighed 20 to 30 mL borosilicate glass vial. The vial was filled with 10 mL of filtered extraction solvent (hexane) and placed in a 60 °C water bath. The filtered extraction solvent was replaced every 20 minutes for a total of three changes. After the last extraction solvent change, two changes of filtered ethanol (10 mL, each) 10 minutes each were performed, then the tissue piece(s) were dried at 110 to 120 °C.

TABLE 1. Studies with Both Mesothelioma and Ovarian Cancer Rates in the Same Cohort and Calculated Comparative Risk of Mesothelioma to Ovarian Cancer in Female-Only Cohorts

Study	Mesothelioma Risk (SMR)	Ovarian Cancer Risk (SMR)	Comparative Risk M/OC
Loomis 2009	10.92	1.23	8.88
Magnani 2008	51.49	2.27	22.68
Pira 2016	51.3	3.03	16.93
Wang 2013	166.67	7.69	21.67
Wilczyńska 2005	22.67	1.76	12.88
Geometric mean of comparative risk			15.69

Tissue samples were digested with 15 to 30 mL of filtered sodium hypochlorite (appx. 8.0% bleach). After digestion, the remaining digested material was filtered through a 25 mm, 0.4 μm polycarbonate (PC) filter. The filter containing the tissue residue was dried and subsequently prepared for TEM examination.

A paraffin control sample (wax blank) was obtained by dissolving a known quantity of the paraffin blocks (devoid of tissue) in 10 mL of filtered extraction solvent and the dissolved solvent/wax solution was then filtered onto a 25 mm, 0.4 μm PC filter. The filter was allowed to dry and then prepared for TEM analysis. A process blank (sample vial) was prepared in the same manner and followed the wax blank and tissue sample vials through all steps.

For TEM analysis, 100 to 300 grid openings were analyzed for all asbestos and talc structures at a magnification of between 4000 and 20,000×. As per standard TEM analysis protocols, asbestos fiber/bundle identification was done by morphology (substantially parallel sides and length to width ratio of at least 5:1), length (greater than 0.5 μm in length), selected area electron diffraction (SAED), and energy dispersive X-ray spectroscopy (EDS).[106–112] Talc structures (platy and fibrous) were identified morphologically, by selected area diffraction (SAED), and energy dispersive spectroscopy (EDS).

RESULTS

Exposure Assessment

Total weight used during the application process was 4.05 g of talc powder. For the five minute sampling time, the average total fiber exposure was 4.52 f/cc (5.86, 4.38, 3.85, and 3.98 f/cc), the average asbestos exposure was 2.57 f/cc (4.51, 1.88, 2.07, and 1.81 f/cc), and the average talc exposure was 1.95 f/cc (1.35, 2.50, 1.78, and 2.16 f/cc) for the talc user personal samples. For area samples, the average total fiber exposure was 0.41 f/cc (0.52, 0.28, 0.42, 0.40 f/cc), the average asbestos exposure was 0.2 f/cc (0.31, 0.20, 0.13, and 0.16 f/cc) and the average fibrous talc exposure was 0.19 f/cc (0.13, 0.08, 0.29, and 0.24 f/cc). The type of asbestos fiber identified in all samples was tremolite asbestos. No fibers were detected in the background samples or field blanks. The complete exposure assessment report, including count sheets and fiber images, is available as Appendix 3, http://links.lww.com/JOM/A688.

Dose Calculations and Risk Assessment

Results for dose calculations, risk assessment, and tissue analysis are summarized in Table 2. See Appendix 5, http://links.lww.com/JOM/A690 for complete past medical history, history of present illness, other ovarian risk factors, exposure history, and dose calculations for each case.

STS was comprised of talcum powder mixed with cornstarch. The STS products contained between 80% and 100% talc sourced from the same mines as JBP.[84] Only four cases used these products for brief or unknown periods of time. Case No. 3 reported infrequent use of unidentified facial make-up powder, and Case No. 6 reported infrequent use of generic store-brand talcum powder. We could not calculate exposures for the brief use of these unknown products.

All cases had pathologically confirmed serous ovarian cancer. Age at diagnosis ranged from 41 to 78 years, with a mean age at diagnosis of 51.1 years and median age at diagnosis of 50 years. By contrast, the median age of ovarian cancer diagnosis in the United States is 63 with most cases occurring in women aged 55 to 64. Seven of 10 cases tested negative for BRCA mutations; two cases were never tested (No. 2 and No. 5), and one case (No. 8) tested positive for BRCA2 variant L771 V.

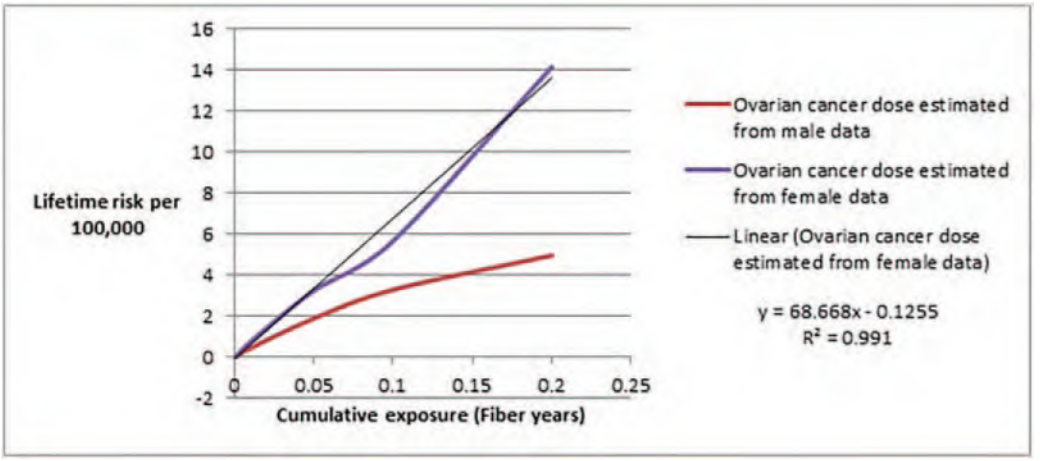

FIGURE 1. Ovarian cancer dose response (adjusted for difference in female mesothelioma risk).

All cases reported perineal talc application; the frequency of perineal powdering with talc ranged from once per day to 10 times per day and the duration ranged from 24 years to 47 years. Nine of 10 cases reported upper body powdering with talc ranging from 1 to 5 times per day and lasting from 20 to 47 years. Seven of 10 cases reported that their parents used talc powder on them during diaper changes and eight of 10 cases used talc powder during diapering. The total asbestos dose from talc powder use ranged from 2,774,000,000 to 37,742,501,440 asbestos fibers (0.38 to 5.18 fiber years) and the average dose was 9,308,551,008 asbestos fibers (1.28 fiber years). No other known asbestos exposure was identified for any of the cases. Based on EPA dose–response estimates, the risk of developing ovarian cancer due to inhaled asbestos exposure was calculated to be 2.3 to 31.1 times greater in these cases compared with baseline risk for ovarian cancer.[105] On average, the risk of ovarian cancer increased 7.7-fold among these cases.

Tissue Analysis

Talc and/or asbestos was identified in the tissue from all cases. Platy talc was found in 9/10 cases (90%) with an average concentration of 264,487 structures per gram (s/g) (range, 0 to 2,057,640 s/g). Fibrous talc was found in 8/10 cases (80%) with an average concentration of 5878 s/g (range, 0 to 21,545 s/g). Tremolite asbestos was found in 6/10 cases (60%) with an average concentration of 6488 s/g (range, 0 to 22,000 s/g). Anthophyllite asbestos was found in 4/10 cases (40%) with an average concentration of 2393 s/g (range: 0 to 12,000 s/g). Ferro-anthophyllite asbestos was also identified in two cases (20%), winchite and richterite asbestos were identified in one case (10%), and crocidolite asbestos was identified in one case (10%). Two tremolite structures with aspect ratios less than 5:1 were observed in one case, but were not counted as asbestos.

In the ''possible fallopian tube B'' tissue of Case No. 2, a cluster measuring $20.0 \times 16.0\,\mu m$ was identified composed of 36 counted talc plates, two fibrous talc structures, and one tremolite fiber. (See Fig. 2.)

DISCUSSION

This case series identified asbestos and/or talc in the tissue of 10 women diagnosed with serous ovarian cancer and exposed to J&J cosmetic talc products. Prior to their ovarian cancer diagnosis, these women were exposed to as much as 2,774,000,000 to 37,742,501,440 asbestos fibers (0.38 to 5.18 fiber years) due to their use of J&J cosmetic talc products. In all reported cases, asbestos exposures due to J&J talc use resulted in a substantial increase in ovarian cancer risk (2.3 to 31.1) based on our model. Early median age of diagnosis (50 in this case series vs. 63 nationally), and the EPA dose response table, indicates that asbestos exposure in infancy may cause ovarian cancer to occur sooner than it would have occurred absent this exposure.[92,105]

The asbestos type found in the perineal talc use inhalation exposure assessment (tremolite asbestos) and the predominant asbestos types identified in these tissue samples (tremolite and anthophyllite asbestos) matched the fiber types previously identified in cosmetic talc products and in talc mines.[41,74,75,77–81] (See Table 3.) Researchers have previously identified anthophyllite asbestos in Johnson's Baby Powder (by TEM analysis),[79] amphibole needles and fibers in baby powder sourced from Vermont,[76,77] and tremolite asbestos fibers in commercial talc produced prior to 1975 from J&J's talc source in Val Chisone, Italy.[81,89]

In 2017, a bundle of tremolite asbestos fibers was found in a bottle of JBP purchased by Case No. 3 in 2014. (See Appendix 6, http://links.lww.com/JOM/A691 for full purchase report.) Tremolite asbestos was also identified in Case No. 3's right pelvic lymph node. (See Fig. 3.) Winchite and richterite asbestos were found in the tissue in one case. However, richterite was called sodium tremolite prior to 1978.[113] Winchite is found in talc from the Allamoore, Texas mine, and may have contaminated J&J Italian talc processed at the same plant in the 1970s.[114–118] Similarly, Transite pipes present in Royston Plant for J&J baby products may have contaminated J&J talc with crocidolite.[119,120] Furthermore, Colgate acknowledges that there is crocidolite in some talc.[121]

The most common structures identified by tissue analysis (platy talc, fibrous talc, tremolite and anthophyllite asbestos) strongly indicate talc powder as the source of asbestos exposure in these cases. Tremolite asbestos has had minor commercial production in India and Italy and is mainly found as an accessory mineral in talc, vermiculite, and chrysotile.[122–124] Anthophyllite asbestos, which occurs as an accessory mineral in talc and chrysotile, has also had limited commercial use.[123–125] Anthophyllite and tremolite together account for less than 1% of asbestos production and consumption worldwide.[124]

None of the cases reported in this series had any known history of alternative asbestos or vermiculite exposure and no chrysotile or vermiculite was found in any of the tissue samples. Churg and Warnock[126] performed a population study of lung asbestos and noted that ''. . . in women a major source [of asbestos fibers] may be cosmetic talc, which is often contaminated with anthophyllite and tremolite.'' Finkelstein's[127] analysis of mesothelial tissue found a statistically significant association for tremolite detected with talc in tissue. This association was higher for women, 82% of whom had talc in their tissue compared with 68% of men.[127] The increased use of talcum-based cosmetics by women, and the similar fiber type combination is a fingerprint of cosmetic talc migrating to the pelvic organs. The combination of talc with tremolite and/or anthophyllite asbestos, as identified by Finkelstein[127] and the 10 cases reported here, are a fingerprint for exposure to asbestos-containing talc.[128–130] (Appendix 7, http://links.lww.com/JOM/A692: a chart of fibers detected in J&J compared with fibers in tissue). These results indicate that perineal use can result in important inhalation exposure to asbestos, which is an accepted route of transmigration to the peritoneum and ovary.[131]

Our exposure assessment found that cosmetic talc users can be exposed to 2.57 f/cc asbestos in the breathing zone during perineal talc application; this finding was generally in agreement with previous studies of asbestos exposures during talc use.[41,93] The bottle of JBP used in this exposure assessment was tested by TEM which detected 15 million fibers per gram. Further analysis found asbestos in 56/90 JBP bottles with a range of 4400 to 15,100,000 asbestos fibers per gram (appendix 4, http://links.lww.com/JOM/A689). For comparison, Gordon et al[41] conducted examination on 50 samples of a single brand of cosmetic talc, sourced from either Montana, North Carolina or Val Chisone. Gordon et al[41] found a range of 1840 to 200 million asbestos fibers per gram. Asbestos is not evenly distributed in talc ores and sampling cannot be completely representative of exposure.[88,132]

Gordon et al[41] selected a bottle with 18 million asbestos fibers per gram for the inhalation study. The results for Gordon's et al.'s[41] simulation of body powdering, 1.9 f/cc, is comparable to our findings of 2.57 f/cc asbestos exposure per application. Application of cosmetic talc varies greatly, including differences in product, application time, grams per use, and location of application. In addition, talc is mined and milled prior to sale, potentially modifying fiber size or dispersing asbestos unequally in finished cosmetic talc product.[133] Talc was sourced from various mines and processing methods changed over time, adding to the variability of asbestos content in talc-containing cosmetic products. However, our findings of an asbestos fingerprint in the tissue reveal that regardless of the dose, exposure to talc-containing cosmetic products is sufficient to cause ovarian cancer.

We relied on NIOSH measurements by Dement et al[93] to calculate exposures during diapering, however these measurements did not account for airborne asbestos exposures that continued after

TABLE 2. Summary of Cases

Case Number	Diagnosis	Age at Diagnosis	Talc Exposure History				Calculated Asbestos Dose	Relative Increase in Ovarian Cancer Risk	Pathological Examination	
			Perineal Powdering	Upper body Powdering	Infant Exposure During Diapering	Adult Exposure During Diapering			Tissue Examined	Findings (Structures Per Gram of Tissue)
1	Metastatic high grade papillary serous carcinoma	45	10x/d, 40yrs	5x/d, 40yrs	8x/d, 2yrs	10x/d, 8yrs	37,742,501,440 fibers, (5.18 fiber years)	31.1	Ovary (R)	Platy talc (333 s/g), Fibrous talc (4,000 s/g), Ferro-anthophyllite (3,667 s/g)
									Ovary (L)	Fibrous talc (1,200 s/g), ferro-anthophyllite (399 s/g)
									Fallopian tube (R)	NSD*
									Fallopian tube (L)	——†
									Pelvic Lymph Node (R)	——†
									Pelvic Lymph Node (L)	NSD*
2	Poorly differentiated high grade serous ovarian carcinoma	53	1x/d, 36yrs	1x/d, 23yrs	8x/d, 2yrs	7.5x/d, 7.5yrs	4,892,501,440 fibers, (0.68 fiber years)	4.1	Ovary A	NSD*
									Ovary B	Platy talc (323 s/g)
									Possible fallopian tube A	NSD*
									Possible fallopian tube B	Platy talc (56,700 s/g), Fibrous talc (4,720 s/g), Tremolite (22,000 s/g)
3	High grade serous carcinoma	49	3x/d, 39yrs	3x/d, 20yrs	8x/d, 2yrs	7x/d, 5yrs	11,535,501,440 fibers, (1.59 fiber years)	9.6	Ovary, fallopian tube (R)	Platy talc (2,001,503 s/g), Fibrous talc (13,343 s/g)
									Adnexa, fallopian tube (L)	Platy talc (12,308 s/g), Fibrous talc (8,202 s/g)
									Pelvic lymph node (R)	Tremolite (15,670 s/g), Winchite (15,670 s/g),‡ Richterite (15,670 s/g)‡
									Pelvic lymph node (L)	Platy talc (43,829 s/g)
4	Poorly differentiated serous adenocarcinoma	78	1x/day, 43yrs§	unknown§	unknown§	unknown§	2,774,000,000 fibers, (0.38 fiber years)	2.3	Ovary (R)	Platy talc (2,860 s/g), Anthophyllite (952 s/g)
									Ovary (L)	Tremolite (604 s/g)
									Fallopian tube (R)	Platy talc (30,000 s/g)
									Fallopian tube (L)	Fibrous talc (868 s/g)
									Pelvic Lymph Node (R)	Platy talc (12,600 s/g)
									Pelvic Lymph Node (L)	Platy talc (17,600 s/g), Tremolite (2,510 s/g)
5	Low grade serous carcinoma	52	1x/d, 47yrs	1x/d, 47yrs	8x/d, 2yrs	10x/d, 10yrs	7,812,501,440 fibers, (1.08 fiber years)	6.5	Ovary (R)	Platy talc (10,900 s/g), Fibrous talc (1,810 s/g)
									Ovary (L)	Platy talc (25,000 s/g), Fibrous talc (5,000 s/g), Tremolite (5,000 s/g)
									Int. Iliac lymph node (R)	Platy talc (77,200 s/g), Fibrous talc (7,720 s/g), Tremolite (3,860 s/g), Anthophyllite (3,860 s/g)
									Comm. Iliac lymph node (R)	Platy talc (50,600 s/g)

(*continues*)

TABLE 2. (*Continued*)

Case Number	Diagnosis	Age at Diagnosis	Talc Exposure History				Calculated Asbestos Dose	Relative Increase in Ovarian Cancer Risk	Pathological Examination	
			Perineal Powdering	Upper body Powdering	Infant Exposure During Diapering	Adult Exposure During Diapering			Tissue Examined	Findings (Structures Per Gram of Tissue)
6	High grade serous papillary carcinoma	51	1x/d, 40yrs	1x/d, 40yrs	8x/d, 2yrs	10x/d, 10yrs	7,009,501,440 fibers, (0.97 fiber years)	5.8	Adnexa, tumor/ovary (R)	Platy talc (21,300 s/g)
									Adnexa, tumor/ovary (L)	Platy talc (4,720 s/g)
									Adnexa, fallopian tube (R)	Platy talc (12,000 s/g), Tremolite (12,000 s/g), Anthophyllite (12,000 s/g)
									Adnexa, fallopian tube (L)	Platy talc (13,700 s/g)
									Pelvic lymph node (L)	Platy talc (11,500 s/g)
7	Serous adenocarcinoma	56	1x/d, 37yrs	1x/d, 37yrs	Unknown	7.5x/d, 6yrs	5,183,000,000 fibers, (0.71 fiber years)	4.3	Ovary (R)	Platy talc (8,740 s/g), fibrous talc (1,090 s/g)
									Ovary (L)	Platy talc (10,500 s/g)
									Fallopian tube (R)	Platy talc (8,500 s/g)
									Fallopian tube (L)	Platy talc (10,900 s/g)
8	High grade ovarian serous carcinoma	44	1x/d, 24yrs	1x/d, 24yrs	Unknown	3.5x/d, 4yrs	2,993,000,000 fibers, (0.41 fiber years)	2.5	Ovary (R)	Platy talc (3,340 s/g), Ferro-anthophyllite (1,670 s/g), Crocidolite (1,670 s/g)
									Ovary (L)	Platy talc (799 s/g)
									Fallopian tube (R)	Platy talc (9,690 s/g), Fibrous talc (1,380 s/g), Tremolite (1,385 s/g), Anthophyllite (1,385 s/g)
									Fallopian tube (L)	Platy talc (7,400 s/g), Tremolite (1,850 s/g)
9	Poorly differentiated serous papillary adenocarcinoma[‖]	41	1x/d, 42yrs[§]	1x/d, 42yrs[§]	8x/d, 2yrs[§]	n/a[§]	4,965,501,440 fibers, (0.69 fiber years)	4.1	Ovary (R)	NSD[*]
									Ovary (L)	NSD[*]
									Fallopian tube (R)	NSD[*]
									Fallopian tube (L)	NSD[*]
									Pelvic Lymph Node (L)	Fibrous talc (8,770 s/g)
10	High-grade ovarian papillary serous carcinoma	42	2x/d, 32yrs	2x/d, 32yrs	8x/d, 2yrs	8x/d, 4yrs	8,177,501,440 fibers, (1.13 fiber years)	6.8	Ovary, fallopian tube (R)	Platy talc (10,800 s/g)[¶]
									Ovary, fallopian tube (L)	Platy talc (5,520 s/g)
									Pelvic lymph node (R)	Platy talc (79,300 s/g)
									Pelvic lymph node (L)	Platy talc (84,400 s/g)

[*]No asbestos or talc structures detected.
[†]Tissue received, but not analyzed.
[‡]Richterite asbestos were known as sodium tremolite.
[§]Patient deceased; exposure history based on recollections of family and friends.
[‖]The final pathology report also noted minor components of transitional cell and mucinous carcinoma.
[¶]Two tremolite structures were reported with an aspect ratio of less that 5:1 that were not counted.

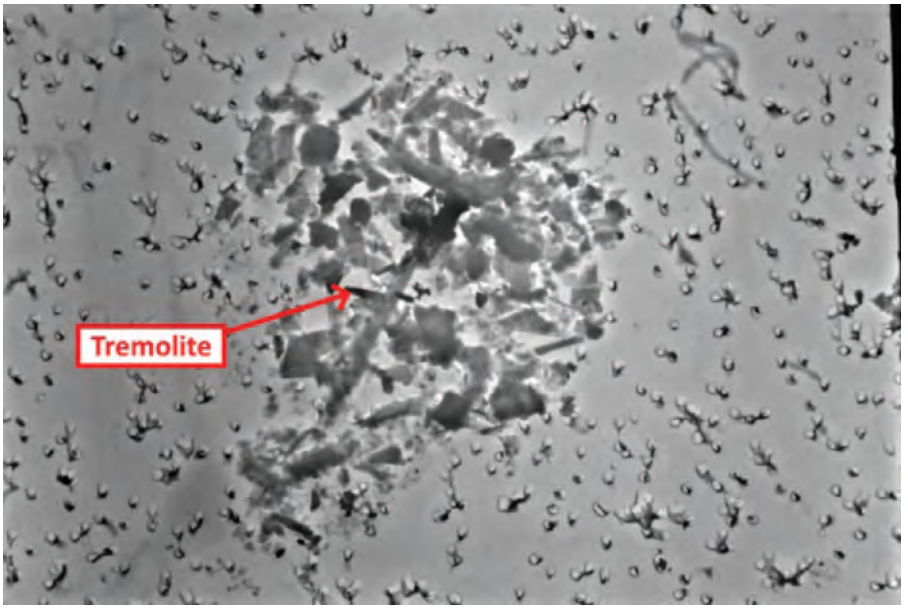

FIGURE 2. TEM image of cluster measuring 20.0 × 16.0 μm composed of 36 counted talc plates, two fibrous talc structures, and one tremolite fiber identified in ''possible fallopian tube B'' tissue of Case No. 2.

the sampling time.[93] Dement et al[93] collected air samples for 2 minutes during a simulated diaper change with JBP, but another experiment in the same study indicated that exposures continued for at least 3 minutes and likely persisted for even longer. Dement et al[93] used phase contrast microscopy and did not differentiate between asbestos and fibrous talc. However, in 1968, NIOSH injected asbestos containing ''cosmetic'' talc into hamsters and detected tremolite asbestos bodies but no fibrous talc in the animal lungs.[134] Anderson et al[100] reported much lower levels during body dusting with talc (0 to 0.0039 f/cc). However, the microscopist in the Anderson et al[100,135] study originally identified four anthophyllite asbestos fibers in the air samples by TEM, but changed the result to transition fibers at the request of the project supervisor due to concern that the results would be used in litigation.[135]

Both our study and Gordon's et al [41] exposures assessment used less talc powder than the average user: these experiments used 4.05 and 0.37 g of talc respectively, but J&J's unpublished studies found that women used 8.16 g and men used 13.02 g of talc powder on average during body powdering.[41,136] Anderson et al[100] reported that subjects used 11.6 g of talc on average to powder their bodies after showering. Therefore, our use estimates were 3 to 20 times lower than Anderson et al[100] and J&J's.

We also excluded many reported talc uses from our dose calculations due to a lack of exposure data. For instance, three cases (No. 1, No. 3, and No. 5) regularly used talc powder on their sheets and pillows; several other cases also reported seeing and smelling dust in the air while cleaning the room where they regularly applied talc. (See Appendix 5, http://links.lww.com/JOM/A690 for complete exposure

TABLE 3. Summary of Studies Reporting Asbestos in Consumer Talc Products

Study	Test Method	Summary of Findings
Rohl et al (1976)	XRD, PLM, TEM, SEM	0.1–14% tremolite and anthophyllite (mostly fibrous) by weight in 10 of 20 consumer talc products tested
Paoletti et al (1984)	TEM	0.5–1.6% tremolite asbestos in two of six Italian cosmetic talc powders tested Trace to 0.15% chrysotile in 3 of 14, 18.7–21.7% anthophyllite asbestos and tremolite asbestos in 2 of 14, and 0.13% tremolite asbestos & chrysotile in 2 of 10 samples provided by the European Pharmacopeia
Blount (1991)	PLM	10 to 341 structures per mg amphibole fibers, needles, cleavages and ''prismatic pieces'' in 9 of 14 samples of pharmaceutical and cosmetic-grade talc powders tested
Jehan (2004)	PLM	Qualitative identification of tremolite asbestos in 13 of 28, chrysotile in 12 of 28, anthophyllite asbestos in 3 of 28, and a mixture of asbestos fibers in 4 of 28 cosmetic talc powder products used in Pakistan
Floyd (2004)	TEM	0.20% anthophyllite asbestos by weight in Johnson's Baby Powder
Mattenklott (2009)	SEM	0.001–0.0073% asbestos by weight in 13 of 57 samples of talc powders sold on the German market from 1996 to 2005
Gordon et al (2014)	PLM	1,840–1,104,000 fibers per gram asbestos in 50 of 50 historical samples of one brand of cosmetic talc powder tested (40 of 50 contained anthophyllite asbestos only, four contained tremolite asbestos only, four contained tremolite and anthophyllite asbestos, two contained tremolite, anthophyllite, and chrysotile asbestos)
	TEM	0.004–0.9% amphibole asbestos by weight in nine of nine samples of the same cosmetic talc product
Ilgren et al (2017)	TEM	3.687×10^6 tremolite asbestos fibers/g in an authentic sample of commercial talc produced prior to 1975 from the talc mine in Val Chisone, Italy

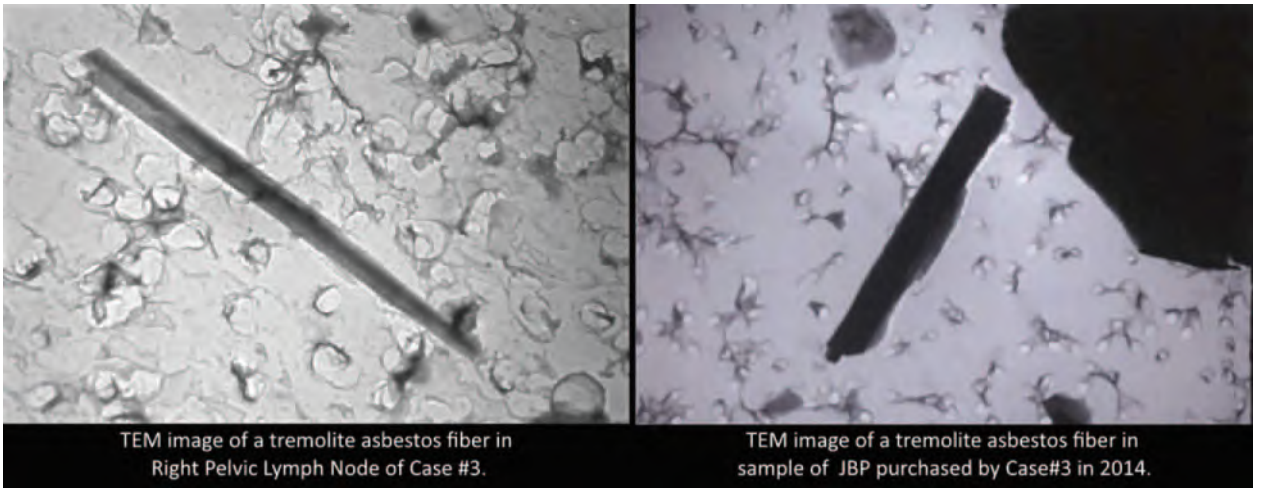

FIGURE 3. TEM images of a tremolite asbestos fibers in Case No. 3 right pelvic lymph node tissue (left) and in sample of JBP purchased by Case No. 3 in 2014 (right).

histories.) Although our findings indicate that asbestos is present in consumer talc products at a level sufficient to cause disease, our dose estimates may under or over estimate the total exposure to asbestos in talc in these cases.

Burns et al[137] created a dose estimation-model for cosmetic talc, relying on previous assessments to predict asbestos exposure, including Moon et al[138], Gordon et al[41], Russell et al[136], and Anderson et. al.[100] Burns's et al[137] assessment was based on an assumption of 0.1% level of asbestos in talc mathematical model that incorrectly reduced the exposure estimate by 1000. For example, Gordon et al[41] reported, 4.8 f/cc, however, Burns's et al[137] math model reduces this figure to 0.0048 f/cc. In comparison, Addison et al (1988)[139] reported that dusts containing 0.1% asbestos may release 1.17 to 2.79 asbestos fibers/cc into the air, consistent with our measurements.

Our tissue analysis results were consistent with previous reports of asbestos and/or talc in ovarian tissue.[136,140–144] (See Table 4.) The number of asbestos structures per gram, however, was approximately one order of magnitude lower in our study than in previous quantitative studies of asbestos in ovarian tissue.[143] This discrepancy may be due to differences in tissue preparation and analytical procedures. Other quantitative studies relied on wet tissue weight for their analysis whereas we used a dry weight procedure.[143] Additionally, we counted 100 to 300 grid openings in our study while other studies appear to have counted the entire grid area.[143] We also found that some tissue samples contained ''hot spots'' with very high concentrations of asbestos and/or talc compared with the surrounding tissue. (See Fig. 2.) The occurrence or absence of ''hot spots'' may also account for variability in reported asbestos concentrations in tissue. The predominant types of asbestos identified in our series (tremolite and anthophyllite asbestos) are the same as those most commonly reported in past studies.[140,143,144]

We did not consider latency in our risk estimate because our calculations followed the EPA risk assessment, which did not consider latency.[92] In addition, Pira et al[68] found that for asbestos-caused ovarian cancer ''. . .the SMRs increased monotonically with time since first employment, although the number of deaths was small in several categories...'' Our omission of latency from this study is to remain consistent with the EPA assessment and reflect the lack of effect demonstrated by Pira's et al analysis.

We omitted fibrous talc from our risk assessment due to a lack of dose–response data in the published literature. IARC has previously classified fibrous talc as a Group 1 carcinogen and OSHA regulates fibrous talc per the asbestos standard.[3,43,145–147] Further research on the relationship between talc powder use and ovarian cancer should include studies of fibrous talc toxicity.

CONCLUSION

Of the 10 reported cases of serous ovarian cancer, all were found to have talc and eight were found to have asbestos in their tissue samples. The main types of asbestos identified in tissue, tremolite and anthophyllite, constitute a fingerprint for talc containing asbestos and indicate that ''cosmetic'' talc powder as the source of asbestos exposure in these cases. IARC has concluded that asbestos is an ovarian carcinogen.[43] IARC has likewise classified talc containing asbestiform fibers (including both asbestos and fibrous talc) as a carcinogen.[3,43,148] These cases provide more evidence of the causal link between asbestos, talc, and ovarian cancer and indicate that asbestos is present in consumer talc products at a level sufficient to cause disease.

In 1973, J&J told the Food and Drug Administration (FDA) that ''Johnson & Johnson's policy of full cooperation with FDA and that if the results of any scientific studies show any question of safety of talc, Johnson & Johnson will not hesitate to take it off the market'' and their corporate position is that there is no known safe level of exposure to asbestos.[149] J&J's studies have shown that asbestos has been present in its cosmetic talc ores since the 1950s. In 2019, the FDA has found asbestos in JBP sourced from China and Claire's cosmetics.[150,151] At least three retailers of cosmetic talc accept the causal relationship between talc use and ovarian cancer: Angel of Mine, Perfect Purity, and Assured Body and Foot Powders warn that ''frequent application of talcum powder in the female genital area may increase the risk of ovarian cancer.''[152] In addition, J&J's talc supplier Rio Tinto Minerals has warned its customers since 2006 of this risk in Material Safety Data Sheets (MSDS) for talc: ''perineal use of talc-based body powder is possibly carcinogenic to humans.''[153,154] J&J removes this warning from its talc MSDS and cosmetic talc products.[155] Because talc powder is a cosmetic product with no medical benefit, these warnings still do not warrant the sale of a products when the benefits cannot outweigh the risks, especially when there is a safer substitute.[156–158]

TABLE 4. Summary of Studies Finding Asbestos and/or Talc in Ovarian Tissue From Cosmetic Talc Use

Study	Tissue Weight Type	Test Method	Summary of Findings
Henderson et al (1971)	n/a	TEM	Qualitative identification of talc in 10/13 ovarian tumors Qualitative identification of talc in 12/21 cervical tumors
Langer (1971)	n/a	Unknown	Qualitative identification of talc and chrysotile asbestos in Henderson et al (1971) samples
Heller, Westhoff et al (1996)	Wet weight	PLM	26–464 talc particles per gram in 12/12 samples of benign ovarian neoplasms from 12 women with history of adult perineal talc use 69–420 talc particles per gram in 11/11 samples of benign ovarian neoplasms from 12 women with history of talc diapering during infancy 6–2,200 talc particles per gram in 6/7 samples of benign ovarian neoplasms from 12 women with no history of adult perineal talc use and an unknown history of other talc uses
		TEM	151,300–7,565,000 talc particles per gram in 5/12 samples of benign ovarian neoplasms from 12 women with history of adult perineal talc use 151,300–1,600,288 talc particles per gram in 6/11 samples of benign ovarian neoplasms from 12 women with history of talc diapering during infancy 63,042–1,669,000 talc particles per gram in 3/7 samples of benign ovarian neoplasms from 12 women with no history of adult perineal talc use and an unknown history of other talc uses
Cramer et al (2007)	n/a	PLM and SEM	Qualitative identification of birefringent particles consistent with talc in pelvic lymph nodes of a 68-year-old woman with stage III ovarian papillary serous carcinoma and a 30-year history of perineal talc use

J&J should comply with its self-proclaimed obligation to take talc-containing cosmetic products off the market ''if the results of any scientific studies show any question of safety of talc, Johnson & Johnson will not hesitate to take it off the market.''[149]

ACKNOWLEDGMENTS

The authors thank Sander Greenland for his review of our risk model and dose calculation equations. Any errors are our responsibility.

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Exhibit C

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW JERSEY

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IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION :

NO. 16-2738 (FLW) (LHG)

THIS DOCUMENT RELATES TO ALL CASES :

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July 12, 2018

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Videotaped deposition of MARGARET M. GUROWITZ, taken pursuant to notice, was held at the law offices of Drinker Biddle & Reath, 105 College Road East, Princeton, New Jersey, beginning at 9:29 a.m., on the above date, before Michelle L. Gray, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

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EXHIBIT C

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VIDEOTAPE TECHNICIAN:
Devyn Mulholland

of the record, Ms. Gurowitz is being produced today pursuant to a March set of deposition notices served by the Plaintiffs' Steering Committee as amended, adjusted, whatever is the right word, by both the Court and the agreement of the parties.

She will be representing both J&J and JJCI today, and she is being presented on Topic 3.4.

MR. LAPINSKI: You just took three quarters of my outline.

- - -

EXAMINATION

- - -

BY MR. LAPINSKI:

Q. Good morning, Ms. Gurowitz. How are you this morning?

A. Good.

Q. I introduced myself to you earlier today. My name is Dan Lapinski, and I'm here on behalf of the Plaintiffs' Steering Committee.

amended notice of 30(b)(6) deposition from defendant Johnson & Johnson Consumer Incorporated.

Ms. Gurowitz, have you seen that document before?

A. I have seen the back part of this document. In terms of the front part, I'm not sure how it differs from the first one.

Q. When you say the back part of the document, what are you referring to?

A. The listing of all the samples.

Q. Okay. And the front part, you're not sure whether you've seen the front part before?

A. Correct.

Q. Okay. Ms. Gurowitz, you understand that you're testifying here today on both -- on behalf of both defendant Johnson & Johnson and defendant Johnson & Johnson Consumer Incorporated?

A. Yes, I understand.

Q. And your testimony is being offered today in your capacity as a corporate representative of both of those defendants, correct?

A. Correct.

Q. You understand that you're not testifying here today as an individual?

A. I understand that.

Q. Okay. And you understand that your testimony today will be binding upon both of those defendants?

A. I understand.

Q. As we move forward generally I'll be referring to J&J or the Johnson & Johnson defendants. And unless I distinguish otherwise, can we just agree that when I refer to J&J or I refer Johnson & Johnson defendants, I'm referring to both of the defendants collectively?

A. Yes.

Q. Okay. And what I would ask is that unless -- unless you distinguish

otherwise, I'm going to assume that your references are references that relate to both of the defendants. Is that a fair assumption?

A. Yes.

Q. Okay. And then I would just ask you if for any reason your answer is going to be specific to Johnson & Johnson or specific to Johnson & Johnson Consumer Incorporated, that you let me know that the response is specific to one of those defendants.

A. I understand.

Q. Thank you. We're also going to be talking today about talcum powder and talcum powder products. And in regard to this deposition, I'd like to have an understanding, as long as you'll agree, that when we reference talcum powder products we're talking about Johnson's Baby Powder and Johnson's Shower to Shower product.

A. I understand.

Q. Okay. To the extent that

there is going to be discussion about a single product, I will try to make clear that I'm talking about a particular product and I would ask that you do the same, if that's okay.

A. I understand.

Q. If you would look at Page 1 of Exhibit 1. At the bottom of Page 1 it has your name listed as a witness, Ms. Gurowitz.

Do you see that?

A. Yes.

Q. And are you here today to testify only as to Topic 3.4 of that deposition notice?

A. Yes.

Q. Okay. And if you would please turn to Page 17 of that deposition notice. At the bottom of Page 17 if you would look at Number 4, chain of custody for identified samples. Are you here today to testify as to the storage and chain of custody for any and all samples that have been identified as being in

defendant's possession?

A. Yes.

(Document marked for identification as Exhibit Gurowitz-3.)

BY MR. LAPINSKI:

Q. Ms. Gurowitz, I'm handing you a document that has been marked as Exhibit 3. And if you would please take a minute to just review that document. Exhibit 3 is the January 31st, 2018 agreed order and stipulation regarding the Johnson & Johnson defendants' production of talcum powder products and talc samples.

If you'd let me know when you're done reviewing that document.

A. Sure. Okay, I've reviewed it.

Q. Very good. Is this the first time that you've seen that document?

A. Yes.

Q. Okay. Do you have an

museums to manage their collections. So Johnson & Johnson has a contract with them. And we utilize that software to manage our collection.

Q. And for how long have you been using that software?

A. Since about 2016 maybe.

Q. And was there any type of software system used prior to 2016 in order for Johnson & Johnson to manage their archives?

A. There was not.

Q. What's the name of that software system?

A. It's called TMS, which stands for The Museum System.

Q. Ms. Gurowitz, what was the role that you played in compiling this list, this section of the sample list that you said you played a role in?

A. This section. I was asked to locate any Johnson's Baby Powder or Shower to Shower products that were in the corporate archives collection. So I

used key word searches to find them. And these are the items that were identified.

Q. Can you explain to me what the corporate archives collection is?

A. The corporate archives collection is a collection of physical artifacts which would be historical products and objects, and also paper artifacts that have been in our museum building for many, many decades.

Q. When you did your -- when you did your search, what keywords did you use --

A. Johnson --

Q. -- to conduct your search?

A. Johnson's Baby Powder, Baby Powder, JBP, Shower to Shower, and STS.

Q. You had also referenced earlier that you had archive consultants who helped you to develop your inventory and archive list; is that correct?

A. That is correct.

Q. What was the name of those archive consultants?

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, MARGARET M. GUROWITZ, have the opportunity to read and sign the deposition transcript.

____

MICHELLE L. GRAY,
A Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter and Notary Public
Dated: July 20, 2018

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

Exhibit D

MAS CHART OF J&J TESTING (current as of September 16, 2021)

TABLE I – CONTAINERS FROM OUTSIDE J&J ARCHIVE PRE 2003 (ITALIAN & VERMONT)

	Photo	Container ID	Sender	Source	Vintage	Asbestos TEM	Asbestos PLM
1		M66514-001	SGPB 4-7-17(1)	JBP – Client Carolyn Weirick Retailer: Cal Oaks	Circa 1980	247,000 s/g Anthophyllite Average Aspect Ratio: 14.8	N/A
2		M65205-001	Kazan	JBP – Collector	1950s	15,100,000 s/g Tremolite Average Aspect Ratio: 12.0 Below Waist Personal Application: 1.81 – 4.51 f/cc	N/A
3		M65208-001	Kazan	JBP – Collector	1957	376,000 s/g Tremolite Richterite Average Aspect Ratio: 10.5	N/A

EXHIBIT D

	Photo	Container ID	Sender	Source	Vintage	Asbestos TEM	Asbestos PLM
4		M65228-001	Kazan	JBP – Collector	1994	445,000 s/g Tremolite Richterite Average Aspect Ratio: 7.9	N/A
5		M65329-041	Lanier	JBP	1940-42	1,310,000 s/g Tremolite Average Aspect Ratio: 11.1	N/A
6		M65329-043	Lanier	JBP	1927-39	938,000 s/g Tremolite Average Aspect Ratio: 9.0	N/A
7		M66173-001	Lanier	JBP	1960	NAD Fibrous Talc	N/A

	Photo	Container ID	Sender	Source	Vintage	Asbestos TEM	Asbestos PLM
8		M66173-002	Lanier	JBP	1927-39	301,000 s/g Tremolite Average Aspect Ratio: 8.1	N/A
9		M66173-003	Lanier	JBP	1945	4,120,000 s/g Tremolite Richterite Average Aspect Ratio: 11.7	N/A
10		M66203-001	Lanier	JBP	1953-58	18,700 s/g Tremolite Average Aspect Ratio: 9.2	N/A
11		M66203-002	Lanier	JBP	1960	NAD Fibrous Talc	N/A

	Photo	Container ID	Sender	Source	Vintage	Asbestos TEM	Asbestos PLM
12		M66203-003	Lanier	JBP	1960 37c	NAD Fibrous Talc	N/A
13		M66203-004	Lanier	JBP	1953 or prior	NAD	N/A
14		M66203-006	Lanier	JBP	1953-58	9,120 s/g Tremolite Average Aspect Ratio: 5.9	N/A
15		M66203-007	Lanier	JBP	1953-58	9,030 s/g Tremolite Average Aspect Ratio: 9.8	N/A

	Photo	Container ID	Sender	Source	Vintage	Asbestos TEM	Asbestos PLM
16		M66309-002	Lanier	JBP	1953 or prior	NAD Fibrous Talc	N/A
17		M66309-003	Lanier	JBP	1950s 53c	NAD Fibrous Talc	N/A
18		M66405-001	Lanier	JBP	1953 or prior	45,200 s/g Tremolite Average Aspect Ratio: 18.6	N/A
19		M66405-002	Lanier	JBP	1953 or prior	NAD Fibrous Talc	N/A

	Photo	Container ID	Sender	Source	Vintage	Asbestos TEM	Asbestos PLM
20		M66203-005	Lanier	JBP	1953 or prior	37,000 s/g Tremolite Average Aspect Ratio: 13.7	N/A
21		M70484-001	SGP 487779	JBP – client Linda Zimmerman Retailer: Thrifty (now Rite Aid) or Ralph's (Kroger)	1994	NAD	ISO PLM: NAD PLM HLS Chrysotile: 0.01-0.10%
22		M71046-001	SGPB 10-23-17	JBP – client Marie Colley Retailer: client did not recall	1996	NAD	ISO PLM: NAD PLM HLS Chrysotile: 0.002-0.01%

Results	**Italian**	**Vermont**	**JBP Total**	**STS Total**	**All Total**
MAS	11/18 = 61%	4/4 = 100%	15/22 = 68%	N/A	15/22 = 68%

TABLE II – CONTAINERS FROM OUTSIDE J&J ARCHIVE POST 2003 (CHINESE)

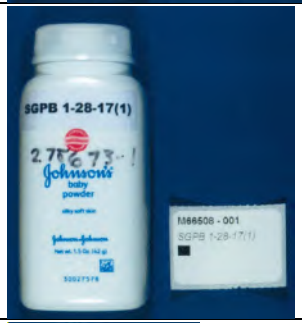
	Photo	Container ID	Sender	Source	Vintage	Asbestos TEM	Asbestos PLM
1		M66507-001	SGPB 11-28-16(1)	JBP – Client Gail Koretoff Retailer: CVS	2004	NAD	CSM PLM w/ HLS Chrysotile: 0.0003-0.001% 51 bundles 779,600 bundles p/g
2		M66508-001	SGPB 1-28-17(1)	JBP – Off the shelf Retailer: CVS	2017	NAD	CSM PLM w/ HLS Chrysotile: 0.001-0.002% 27 bundles 412,700 bundles p/g
3		M66509-001	SGPB 1-28-17(2)	JBP – Off the shelf Retailer: CVS	2017	NAD	CSM PLM w/ HLS Chrysotile: 0.0002-0.001% 39 bundles 463,700 bundles p/g
4		M66513-001	SGPB 3-21-17(4)	JBP – Client Earl Wheeler Retailer: Fred's Dollar	2010	NAD	CSM PLM w/ HLS Chrysotile: 0.0002-0.001% 17 bundles 181,900 bundles p/g

	Photo	Container ID	Sender	Source	Vintage	Asbestos TEM	Asbestos PLM
5		M66515-001	SGPB 4-19-17(6)	JBP – Client Pauline Citizen Retailer: Usually Dollar Store or Family Dollar	2012	8,740 s/g Tremolite Average Aspect Ratio: 28.6	<u>PLM/HLS Chrysotile:</u> 0.01-0.10 %
6		M66516-001	SGPB 4-1-17(7)	JBP – Client Pauline Citizen Retailer: Usually Dollar Store or Family Dollar	2012	8,690 s/g Tremolite Average Aspect Ratio: 9.3	N/A
7		M68379-001	SGPB 11-22-17(1)	JBP – Client JoAnne Anderson Retailer: client did not recall	2004	NAD Fibrous Talc	N/A
8		M68379-002	SGPB 11-22-17(2)	JBP – Client JoAnne Anderson Retailer: client did not recall	2004	7,160 s/g Tremolite	N/A

	Photo	Container ID	Sender	Source	Vintage	Asbestos TEM	Asbestos PLM
9		M66352-001	Lanier	JBP – client Krystal Kim Retailer: client did not recall	2012	NAD	N/A
10		M66352-002	Lanier	JBP – client Krystal Kim Retailer: client did not recall	2014	17,200 s/g Tremolite Average Aspect Ratio: 8.8	N/A
11		M68483-001	SGPB 188908	JBP – Client Nancy Cabibi Retailers: client did not recall	2012	NAD	N/A
12		M67420-001	#1 Lanier	JBP – Off the shelf Retailer: Imperial Westwood	2017	NAD	<u>CSM PLM w/ HLS</u> <u>Chrysotile:</u> 0.0002-0.0008% 30 bundles 428,000 bundles p/g

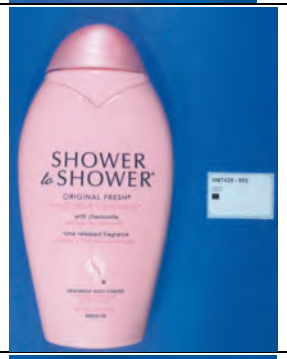
	Photo	Container ID	Sender	Source	Vintage	Asbestos TEM	Asbestos PLM
13		M67420-002	#2 Lanier	JBP – Off the shelf Retailer: Imperial Westwood	2017	NAD	CSM PLM w/ HLS Chrysotile: 0.0002-0.0006% 32 bundles 489,100 bundles p/g
14		M67420-003	#3 Lanier	STS – Off the shelf Retailer: Imperial Westwood	Pre 2012 Purchased 2017	18,800 s/g Anthophyllite Average Aspect Ratio: 22.1	N/A
15		M67420-004	#4 Lanier	JBP – Off the shelf Retailer: Westside Medical Pharmacy	2017	NAD	CSM PLM w/ HLS Chrysotile: 0.0002-0.0005% 28 bundles 332,900 bundles p/g
16		M67420-005	#5 Lanier	JBP – Off the shelf Retailer: Westside Medical Pharmacy	2017	NAD	CSM PLM w/ HLS Chrysotile: 0.0002-0.001% 43 bundles 460,100 bundles p/g

	Photo	Container ID	Sender	Source	Vintage	Asbestos TEM	Asbestos PLM
17		M65329-013	MAS	JBP – Off the shelf (Control) Retailer: Publix	2016	NAD	<u>CSM PLM w/ HLS Chrysotile:</u> 0.0005-0.0008% 27 bundles 288,900 bundles p/g
18		M70484-002	SGP 445997	JBP – client Linda Zimmerman Retailer: CVS, Rite Aid, Albertson's	2014	NAD	<u>ISO PLM:</u> NAD <u>PLM HLS Chrysotile:</u> 0.001-0.01%
19		M70877-001	Kazan 001	JBP – client Dan Doyle Retailer: Usually Kroger's	2012	NAD	<u>ISO PLM:</u> NAD <u>Blount PLM:</u> NAD <u>PLM HLS Chrysotile:</u> 0.01-0.02%
20		M70877-002	Kazan 002	JBP – client Dan Doyle Retailer: Usually Kroger's	2010	6,610 s/g Tremolite Average Aspect Ratio: 7.3	<u>ISO PLM:</u> NAD <u>Blount PLM:</u> NAD <u>PLM HLS Chrysotile:</u> 0.002-0.004%

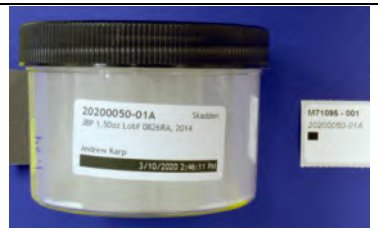
	Photo	Container ID	Sender	Source	Vintage	Asbestos TEM	Asbestos PLM
21		M71095-001	Simmons Lot#0826RA	JBP – client Janet Titley	2014	NAD	ISO PLM: 0.005-0.007% Chrysotile Blount PLM w/ HLS: NAD CSM PLM w/ HLS Chrysotile: 0.001-0.002%
22		M71166-001	MAS	JBP – Off the shelf Retailer: CVS	Purchased 2020 ©2018	N/A	ISO PLM: 0.006-0.008% Chrysotile Blount PLM w/ HLS: NAD CSM-PLM w/ HLS Chrysotile: 0.0015-0.0017%
23		M71166-002	MAS	JBP – Off the shelf Retailer: CVS	Purchased 2020 ©2019	N/A	ISO PLM: 0.009-0.010% Chrysotile Blount PLM w/ HLS: NAD CSM-PLM w/ HLS Chrysotile: 0.0013-0.0030%
24		M71166-003	MAS	JBP – Off the shelf Retailer: Walgreens	Purchased 2020 ©2019	N/A	ISO PLM: 0.009-0.010% Chrysotile Blount PLM w/ HLS: NAD CSM-PLM w/ HLS Chrysotile: 0.0012-0.0026%

	Photo	Container ID	Sender	Source	Vintage	Asbestos TEM	Asbestos PLM
25		M71180-001	Humphrey, Farrington & McLain	JBP – Off the shelf Retailer: Target	Purchased 2020	N/A	ISO PLM: 0.007-0.010% Chrysotile Blount PLM w/ HLS: NAD CSM-PLM w/ HLS Chrysotile: 0.0016-0.0030%
26		M71211-001 20200342-01	Weitz	JBP – Off the shelf from client Holly Johnson Retailer: Walmart.com	2019	N/A	ISO PLM w/o HLS: 0.004-0.006% Chrysotile CSM/ISO PLM w/ HLS Chrysotile: 0.001-0.002%
27		M71211-002 20200342-02	Weitz	JBP – Off the shelf from client Holly Johnson Retailer: Walmart.com	2019	N/A	ISO PLM w/o HLS: 0.003-0.005% Chrysotile CSM/ISO PLM w/ HLS Chrysotile: 0.001-0.002%
28		M71211-003 20200342-03	Weitz	JBP – Off the shelf from client Holly Johnson Retailer: Kents Grocery	2019	N/A	ISO PLM w/o HLS: 0.003-0.005% Chrysotile CSM/ISO PLM w/ HLS Chrysotile: 0.001%

	Photo	Container ID	Sender	Source	Vintage	Asbestos TEM	Asbestos PLM
29		M71211-004 20200342-04	Weitz	JBP – Off the shelf from client Holly Johnson Retailer: Kents Grocery	2019	N/A	ISO PLM w/o HLS: 0.003-0.005% Chrysotile CSM/ISO PLM w/ HLS Chrysotile: 0.0009-0.001%
30		M71211-005 20200342-05	Weitz	JBP – Off the shelf from client Holly Johnson Retailer: Maceys Grocery	2019	N/A	ISO PLM w/o HLS: 0.003-0.006% Chrysotile CSM/ISO PLM w/ HLS Chrysotile: 0.001-0.002%
31		M71211-006 20200342-06	Weitz	JBP – Off the shelf from client Holly Johnson Retailer: Maceys Grocery	2019	N/A	ISO PLM w/o HLS: 0.003-0.004% Chrysotile CSM/ISO PLM w/ HLS Chrysotile: 0.001-0.002%
32		M71211-007 20200342-07	Weitz	JBP – Off the shelf from client Holly Johnson Retailer: Walmart.com	2019	N/A	ISO PLM w/o HLS: 0.003-0.005% Chrysotile CSM/ISO PLM w/ HLS Chrysotile: 0.001-0.002%

	Photo	Container ID	Sender	Source	Vintage	Asbestos TEM	Asbestos PLM
33		M71211-008 20200342-08	Weitz	JBP – Off the shelf from client Holly Johnson Retailer: Walmart.com	2019	N/A	ISO PLM w/o HLS: 0.004-0.007% Chrysotile CSM/ISO PLM w/ HLS Chrysotile: 0.001-0.002%
34		M71211-009 20200342-09	Weitz	JBP – Off the shelf from client Holly Johnson Retailer: Amazon	2019	N/A	ISO PLM w/o HLS: 0.004-0.006% Chrysotile CSM/ISO PLM w/ HLS Chrysotile: 0.001-0.002%
35		M71211-010 20200342-10	Weitz	JBP – Off the shelf from client Holly Johnson Retailer: Amazon	2019	N/A	ISO PLM w/o HLS: 0.004-0.006% Chrysotile CSM/ISO PLM w/ HLS Chrysotile: 0.001-0.002%
36		M71216-001	Kazan	JBP – Off the shelf Retailer: Lucky in Danville, CA	2019	N/A	ISO PLM w/o HLS Chrysotile: 0.007-0.009% 20 bundles 214,000 bundles p/g CSM/ISO PLM w/ HLS Chrysotile: 0.001-0.002% 23 bundles 273,000 bundles pg/

	Photo	Container ID	Sender	Source	Vintage	Asbestos TEM	Asbestos PLM
37		M71216-002	Kazan	JBP – Off the shelf Retailer: Lucky in Danville, CA	2019	N/A	ISO PLM w/o HLS Chrysotile: 0.006-0.008% 16 bundles 190,000 bundles p/g CSM/ISO PLM w/ HLS Chrysotile: 0.0009-0.001% 19 bundles 254,000 bundles p/g
38		M71241-001	MAS	JBP – Off the shelf Retailer: Ralphs	2018	N/A	ISO PLM w/o HLS Chrysotile: NAD CSM/ISO PLM w/ HLS Chrysotile: 0.0007-0.001% 11 bundles 168,142 bundles p/g
39		M71241-002	MAS	JBP – Off the shelf Retailer: Ralphs	2018	N/A	ISO PLM w/o HLS Chrysotile: 0.004-0.006% 9 bundles 80,400 bundles p/g CSM/ISO PLM w/ HLS Chrysotile: 0.001-0.002% 23 bundles 273,000 bundles p/g

	Photo	Container ID	Sender	Source	Vintage	Asbestos TEM	Asbestos PLM
40		M71241-003	MAS	JBP – Off the shelf Retailer: Ralphs	2018	N/A	ISO PLM w/o HLS Chrysotile: 0.005-0.006% 16 bundles 190,600 bundles p/g CSM/ISO PLM w/ HLS Chrysotile: 0.001% 23 bundles 307,600 bundles p/g

Results	Chinese	JBP Total	STS Total	All Total
MAS	37/40 = 93%	36/39 = 92%	1/1 = 100%	37/40 = 93%

TABLE III – VALEANT CONTAINERS FROM OUTSIDE J&J ARCHIVE POST 2003 (CHINESE)

	Photo	Container ID	Sender	Source	Vintage	Asbestos TEM	Asbestos PLM
1		M66510-001	SGPB 2-27-17(3)	S2S – Client John Currie Retailer: Usually Walmart	2013	18,200 s/g Actinolite Richterite Average Aspect Ratio: 33.2	N/A
2		M66511-001	SGPB 3-7-17(1)	S2S – Off the shelf Retailer: Walmart	2017	NAD	N/A
3		M66512-001	SGPB 3-21-17(2)	S2S – Client Earl Wheeler Retailer: Dollar General, Fred's Dollar, or Walmart	2013	8,800 s/g Richterite Average Aspect Ratio: 10.0	N/A

Results	Chinese	STS Total	All Total
MAS	2/3 = 67%	2/3 = 67%	2/3 = 67%

TABLE IV – J&J ARCHIVE CONTAINERS (U.S.)

	Photo	Container ID	MAS Sample ID	Sender	Vintage	Asbestos TEM	Asbestos PLM
1		2018-0060-04 JBP 167	M68503-010	MDL	1960	31,400 s/g Tremolite Average Aspect Ratio: 9.1	ISO: NAD Blount: <0.1 Trem/Act
2		2018-0060-03 JBP 166	M68503-009	MDL	1962	17,700 s/g Tremolite Average Aspect Ratio: 6.8	ISO: NAD Blount: <0.1 Trem/Act
3		2018-0060-76 JBP 119	M68503-024	MDL	1963	NAD	NAD
4		2018-0056-25 JBP 232	M68503-004	MDL	1964	NAD	ISO: <0.1 Trem/Act Blount: NAD

	Photo	Container ID	MAS Sample ID	Sender	Vintage	Asbestos TEM	Asbestos PLM
5		2018-0060-20 JBP 183	M68503-014	MDL	1965	17,300 s/g Tremolite Average Aspect Ratio: 8.0	NAD
6		2018-0060-06 JBP 169	M68503-011	MDL	1966	NAD	NAD
7		2018-0061-09 STS 043	M68503-027	MDL	1966	NAD	NAD
8		2018-0060-44 JBP 087	M68503-019	MDL	1967	8,930 s/g Anthophyllite Average Aspect Ratio: 20.0	NAD

	Photo	Container ID	MAS Sample ID	Sender	Vintage	Asbestos TEM	Asbestos PLM
9		2018-0056-31 JBP 238	M69042-003	MDL	1967	18,000 s/g Tremolite Anthophyllite Average Aspect Ratio: 9.2	ISO: <0.1 Trem/Act <0.1 Anth Blount: <0.1 Trem/Act <0.1 Anth
10		2018-0060-25 JBP 188	M69042-005	MDL	1967	NAD	NAD
11		2018-0060-49 JBP 092	M69042-006	MDL	1967	NAD	NAD
12		2018-0060-50 JBP 093	M69042-007	MDL	1967	NAD	NAD

	Photo	Container ID	MAS Sample ID	Sender	Vintage	Asbestos TEM	Asbestos PLM
13		2018-0061-40 STS 004	M68503-038	MDL	1968	NAD	NAD
14		2018-0061-08 STS 042	M68503-026	MDL	1969	268,000 s/g Tremolite Average Aspect Ratio: 8.7	ISO: <0.1 Trem/Act Blount: <0.1 Trem/Act
15		2018-0056-30 JBP 237	M68503-005	MDL	1970	NAD	NAD
16		2018-0060-68 JBP 111	M69042-009	Levy (MDL)	1970	NAD	ISO: <0.1 Trem/Act Blount: NAD

	Photo	Container ID	MAS Sample ID	Sender	Vintage	Asbestos TEM	Asbestos PLM
17		2018-0061-17 STS 051	M68503-029	MDL	1971	NAD	NAD
18		2018-0060-54 JBP 097	M68503-021	MDL	1972	NAD	NAD
19		2018-0060-64 JBP 107	M68503-023	MDL	1973	8,760 s/g Anthophyllite Average Aspect Ratio: 10.7	ISO: <0.1 Anth Blount: <0.1 Anth
20		2018-0061-12 STS 046	M68503-028	MDL	1974	17,500 s/g Anthophyllite Average Aspect Ratio: 10.5	ISO: NAD Blount: <0.1 Anth

	Photo	Container ID	MAS Sample ID	Sender	Vintage	Asbestos TEM	Asbestos PLM
21		2018-0061-02D STS 1611A (STS 36)	02D	J3 (MDL)	1975	NAD	ISO: NAD (J3) Blount: NAD
22		2018-0056-02D JBP 209	M69042-001	Levy (MDL)	1975	22,400 s/g Anthophyllite Average Aspect Ratio: 21.7	ISO: <0.1 Trem/Act Blount: <0.1 Trem/Act
23		2018-0061-57 STS 021	M68503-046	MDL	1975	NAD	NAD
24		2018-0061-49 STS 013	M68503-042	MDL	1976	23,600 s/g Anthophyllite Average Aspect Ratio: 9.8	ISO: <0.1 Trem/Act <0.1 Anth Blount: <0.1 Trem/Act

	Photo	Container ID	MAS Sample ID	Sender	Vintage	Asbestos TEM	Asbestos PLM
25		2018-0015-01A1 JBP 084	M68233-001	MDL (Lanier)	1978	7,240 s/g Anthophyllite Average Aspect Ratio: 7.6	ISO: <0.1 Trem/Act Blount: <0.1 Trem/Act
		2018-0015-01A2 JBP 084	M68233-002			22,130 s/g Anthophyllite Average Aspect Ratio: 19.4	ISO: <0.1 Trem/Act Blount: <0.1 Anth
26		2018-0070-10 2014-001-0612 JBP	M68503-057	MDL	1977	8,360 s/g Tremolite Average Aspect Ratio: 5.3	ISO: <0.1 Trem/Act <0.1 Anth Blount: NAD
27		2018-0060-53 JBP 096	M68503-020	MDL	1978	34,800 s/g Anthophyllite Tremolite Average Aspect Ratio: 13.8	ISO: <0.1 Trem/Act <0.1 Anth Blount: <0.1 Trem/Act

	Photo	Container ID	MAS Sample ID	Sender	Vintage	Asbestos TEM	Asbestos PLM
28		2018-0056-06 JBP 213	M69042-002	Levy (MDL)	1978	63,800 s/g Anthophyllite Average Aspect Ratio: 14.0	ISO: <0.1 Trem/Act <0.1 Anth Blount: <0.1 Trem/Act <0.1 Anth
29		2018-0056-34 JBP 241	M69042-004	Levy (MDL)	1978	18,000 s/g Anthophyllite Average Aspect Ratio: 21.9	ISO: <0.1 Trem/Act <0.1 Anth Blount: <0.1 Trem/Act <0.1 Anth
30		2018-0060-67 JBP 110	M69042-008	Levy (MDL)	1978	18,100 s/g Anthophyllite Average Aspect Ratio: 7.9	ISO: <0.1 Anth Blount: <0.1 Anth
31		2018-0070-07D 2014-001-0397 STS	07D	J3 (MDL)	1978	82,000 s/g Anthophyllite Average Aspect Ratio: 18.5	ISO: NAD (J3) Blount: 0.2 Trem/Act 0.5 Anth

	Photo	Container ID	MAS Sample ID	Sender	Vintage	Asbestos TEM	Asbestos PLM
32		2018-0061- 15D STS 049	15D	J3 (MDL)	1978	61,000 s/g Anthophyllite Average Aspect Ratio: 20.0	ISO: NAD (J3) Blount: 0.3 Anth
33		2018-0061- 50D STS 1605A STS 014	50D	J3 (MDL)	1978	NAD	ISO: NAD (J3) Blount: <0.1 Anth
34		2018-0070-16 2-14-001-1363 JBP	M68503-059	MDL	1979	17,100 s/g Anthophyllite Average Aspect Ratio: 18.4	ISO: <0.1 Trem/Act <0.1 Anth Blount: <0.1 Trem/Act <0.1 Anth
35		2018-0061- 10D STS 044	10D	J3 (MDL)	1980	N/A	ISO: NAD (J3) Blount: 0.2 Trem/Act <0.1 Anth

	Photo	Container ID	MAS Sample ID	Sender	Vintage	Asbestos TEM	Asbestos PLM
36		2018-0061-38D STS 002	38D	J3 (MDL)	1980	53,000 s/g Anthophyllite Average Aspect Ratio: 9.6	ISO: NAD (J3) Blount: 0.2 Tre/Act 0.2 Anth
37		2018-0061-63D STS 027D	63D	J3 (MDL)	1980	N/A	ISO: NAD (J3) Blount: 0.2 Tre/Act 0.2 Anth
38		2018-0061-52D STS 016	52D	J3 (MDL)	1981	70,000 s/g Anthophyllite Average Aspect Ratio: 22.4	ISO: NAD (J3) Blount: 0.2 Tre/Act 0.5 Anth
39		2018-0061-65D STS 029	65D	J3 (MDL)	1981	95,000 s/g Anthophyllite Average Aspect Ratio: 18.4	ISO: NAD (J3) Blount: 0.2 Tre/Act 0.2 Anth

	Photo	Container ID	MAS Sample ID	Sender	Vintage	Asbestos TEM	Asbestos PLM
40		2018-0061-37D STS 001	37D	J3 (MDL)	1982	9,300 s/g Anthophyllite Average Aspect Ratio: 6.1	ISO: NAD (J3) Blount: <0.1 Tre/Act <0.1 Anth
41		2018-0061-45D STS 009	45D	J3 (MDL)	1982	9,000 s/g Anthophyllite Average Aspect Ratio: 8.0	ISO: NAD (J3) Blount: <0.1 Tre/Act
42		2018-0061-51D STS 1606A STS 015	51D	J3 (MDL)	1982	NAD	ISO: NAD (J3) Blount: <0.1 Tre/Act
43		2018-0061-66D STS 1610A STS 030	66D	J3 (MDL)	1982	NAD	ISO: NAD (J3) Blount: 0.1 Tre/Act

	Photo	Container ID	MAS Sample ID	Sender	Vintage	Asbestos TEM	Asbestos PLM
44		2018-0061-21D STS 1614A STS 055	21D	J3 (MDL)	1983	NAD	ISO: NAD (J3) Blount: <0.1 Tre/Act <0.1 Anth
45		2018-0051-34 JBP 294 *Twin pack. Only 1 bottle selected for sampling by MDL. (See note on COC from MDL split)	M68503-001	MDL	1984	18,700 s/g Anthophyllite Tremolite Average Aspect Ratio: 11.5	ISO: <0.1 Tre/Act Blount: <0.1 Tre/Act
46		2018-0070-86 2014.001.5102 JBP	M69042-010	Levy (MDL)	1985	12,500 s/g Anthophyllite Average Aspect Ratio: 11.5	ISO: <0.1 Tre/Act Blount: <0.1 Anth
47		2018-0061-31F STS 065 “Regular” (Left)	31F	J3 (MDL)	1986	22,000 s/g Anthophyllite Average Aspect Ratio: 16.6	ISO: NAD (J3) Blount: 0.3 Tre/Act <0.1 Anth

	Photo	Container ID	MAS Sample ID	Sender	Vintage	Asbestos TEM	Asbestos PLM
48		2018-0061-31G STS 065 "Spice" (Right)	31G	J3 (MDL)	1986	30,000 s/g Anthophyllite Average Aspect Ratio: 21.8	ISO: NAD (J3) Blount: <0.7 Tre/Act
49		2018-0060-33 JBP 001	M68503-016	MDL	1994	NAD	NAD
50		2018-0060-38 JBP 006	M68503-017	MDL	1996	NAD	NAD

Results	Italian	Vermont	JBP	STS	All Total
MAS	7/14 = 50%	29/36 = 81%	18/27 = 67%	18/23 = 78%	36/50 = 72%

TABLE V – J&J ARCHIVE CONTAINERS (ASIA)

	Photo	Container ID	MAS Sample ID	Sender	Vintage	Asbestos TEM	Asbestos PLM
1		2018-0060-36D JBP 004	M69248-001	Levy (MDL)	Unknown Asian	NAD	NAD
2		2014.001.3718 2018-0070-28D JBP	M69248-002	Levy (MDL)	1979 Asian	29,100 s/g Tremolite Average Aspect Ratio: 8.2	PLM: NAD Blount: <0.1 Trem/Act
3		2014.001.3918 2018-0070-29D JBP	M69248-003	Levy (MDL)	1980-1984 Asian	65,100 s/g Tremolite Average Aspect Ratio: 9.1	PLM: NAD Blount: 0.3 Trem/Act

	Photo	Container ID	MAS Sample ID	Sender	Vintage	Asbestos TEM	Asbestos PLM
4		2014.001.0499 2018-0070-39D JBP	M69248-004	Levy (MDL)	Unknown Asian	17,600 s/g Tremolite Average Aspect Ratio: 6.2	PLM: NAD Blount: 0.1 Trem/Act
5		2014.001.2021 2018-0070-45D JBP	M69248-005	Levy (MDL)	Unknown Asian	35,100 s/g Tremolite Average Aspect Ratio: 10.0	PLM: NAD Blount: 0.2 Trem/Act
6		2014.001.3921 2018-0070-60D JBP	M69248-006	Levy (MDL)	1982 Asian	35,000 s/g Tremolite Average Aspect Ratio: 13.9	PLM: NAD Blount: 0.1 Trem/Act
7		2014.001.5859 2018-0070-93D JBP	M69248-007	Levy (MDL)	Unknown Asian	45,400 s/g Tremolite Average Aspect Ratio: 10.1	PLM: NAD Blount: <0.1 Trem/Act

	Photo	Container ID	MAS Sample ID	Sender	Vintage	Asbestos TEM	Asbestos PLM
8		2014.1.3298 2018-0070-23A JBP	M69925-001	SGP (MDL)	1970-1980 Philippines	17,300 s/g Tremolite Average Aspect Ratio: 16.3	PLM: NAD Blount: <0.1% Trem/Act
9		2018-0060-35A JBP 003	M69925-002	SGP (MDL)	1996 Philippines	NAD	NAD

Results	Asian	JBP Total	STS Total	All Total
MAS	7/9 = 78%	7/9 = 78%	N/A	7/9 = 78%

TABLE VI – J&J ARCHIVE CONTAINERS (U.K. and AUSTRALIA)

	Photo	Container ID	MAS Sample ID	Sender	Vintage	Asbestos TEM	Asbestos PLM
1		2018-0061-72D U.K. Facility #3	M70850-001	Levy (MDL)	Late 1950s Made in Gt. Britain	6,000 s/g Tremolite Fibrous Talc Average Aspect Ratio: 32.4	NAD
2		2018-0061-73D U.K. Facility #1	M70850-002	Levy (MDL)	Late 1940s Made in Gt. Britain	26,300 s/g Tremolite Fibrous Talc Average Aspect Ratio: 13.2	NAD
3		2018-0061-74D U.K. Facility #4	M70850-003	Levy (MDL)	October 1966 Made in England	NAD Fibrous Talc	NAD
4		2019-0189-01D 2014.1.5830	M70850-004	Levy (MDL)	1940 Made in Gt. Britain	11,800 s/g Tremolite Fibrous Talc Average Aspect Ratio: 8.4	NAD

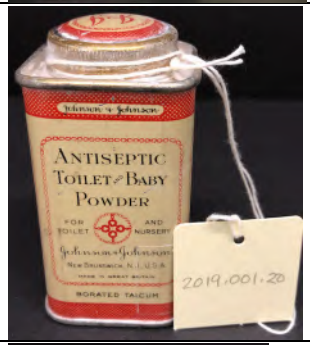
	Photo	Container ID	MAS Sample ID	Sender	Vintage	Asbestos TEM	Asbestos PLM
5		2019-0189-02D 2015.001.3449	M70850-005	Levy (MDL)	Unknown Made in Gt. Britain	NAD Fibrous Talc	NAD
6		2019-0189-04D 2019.001.0020	M70850-006	Levy (MDL)	c. 1916 Made in Great Britain	23,800 s/g Tremolite Average Aspect Ratio: 12.5 Fibrous Talc	PLM: NAD Blount: <0.1% Trem/Act
7		2019-0189-05D 2019.001.0021	M70850-007	Levy (MDL)	1943 Johnson & Johnson (Gt. Britain)	18,100 s/g Tremolite Average Aspect Ratio: 11.2 Fibrous Talc	NAD
8		2019-0189-35D 2014.1.0145	M70850-008	Levy (MDL)	1983-1989 Johnson & Johnson Australia PTY	18,100 s/g Tremolite Average Aspect Ratio: 7.8	PLM: <0.1% Trem/Act Blount: <0.1% Trem/Act

	Photo	Container ID	MAS Sample ID	Sender	Vintage	Asbestos TEM	Asbestos PLM
9		2018-0070-38D 2014.1.0403	M70850-009	Levy (MDL)	1987/1989 Johnson & Johnson Australia PTY	12,000 s/g Tremolite Average Aspect Ratio: 10.8	NAD
10		2018-0070-13D 2014.1.0939	M70850-010	Levy (MDL)	1980 Made in England	17,900 s/g Tremolite Average Aspect Ratio: 11.2 Fibrous Talc	PLM: NAD Blount: <0.1% Trem/Act
11		2018-0070-19D 2014.1.2462	M70850-011	Levy (MDL)	Unknown Made in UK	NAD	NAD
12		2018-0070-30D 2014.1.3976	M70850-012	Levy (MDL)	1972 Made in England	NAD Fibrous Talc	NAD

	Photo	Container ID	MAS Sample ID	Sender	Vintage	Asbestos TEM	Asbestos PLM
13		2018-0070-80D 2015.1.3448	M70850-013	Levy (MDL)	1940s Made in Gt. Britain	5,960 s/g Tremolite Average Aspect Ratio: 7.8 Fibrous Talc	NAD

Results	U.K.	Australian	JBP Total	STS Total	All Total
MAS	7/11 = 64%	2/2 = 100%	8/12 = 67%	1/1 = 100%	9/13 = 69%

TABLE VII – CONTAINERS FROM OUTSIDE J&J ARCHIVE – UNITED KINGDOM

	Photo	Container ID	Sender	Source	Vintage	Asbestos TEM	Asbestos PLM
1		M70859-001	P2	JBP – From client Chris Powell (P2) Retailer: direct from J&J UK office/factory	2002	<6,900 s/g	Blount PLM w/ HLS: NAD ISO PLM w/o HLS Chrysotile: In progress CSM-PLM w/ HLS Chrysotile: 0.017-0.019% 69 bundles 921,000 bundles p/g
2		M70859-002	P2	JBP – From client Chris Powell (P2) Retailer: direct from J&J UK office/factory	2002	<7,110 s/g	Blount PLM w/ HLS: NAD ISO PLM w/o HLS Chrysotile: In progress CSM-PLM w/ HLS Chrysotile: 0.019-0.020% 74 bundles 1,002,000 bundles p/g
3		M70859-003	P2	JBP – From client Chris Powell (P2) Retailer: direct from J&J UK office/factory	2002	<6,880 s/g	Blount PLM w/ HLS: NAD ISO PLM w/o HLS Chrysotile: In progress CSM-PLM w/ HLS Chrysotile: 0.021-0.023% 83 bundles 713,000 bundles p/g

	Photo	Container ID	Sender	Source	Vintage	Asbestos TEM	Asbestos PLM
4		M70859-004	P2	JBP – From client Chris Powell (P2) Retailer: direct from J&J UK office/factory	2002	<7,240 s/g	<u>Blount PLM w/ HLS:</u> NAD <u>ISO PLM w/o HLS</u> <u>Chrysotile:</u> In progress <u>CSM-PLM w/ HLS</u> <u>Chrysotile:</u> 0.018-0.019% 73 bundles 656,000 bundles p/g
5		M70859-005	P2	JBP – From client Chris Powell (P2) Retailer: direct from J&J UK office/factory	2002	<6,960 s/g	<u>Blount PLM w/ HLS:</u> NAD <u>ISO PLM w/o HLS</u> <u>Chrysotile:</u> In progress <u>CSM-PLM w/ HLS</u> <u>Chrysotile:</u> 0.013-0.014% 58 bundles 491,000 bundles p/g
6		M70859-006	P2	JBP – From client Chris Powell (P2) Retailer: direct from J&J UK office/factory	2002	<7,260 s/g	<u>Blount PLM w/ HLS:</u> NAD <u>ISO PLM w/o HLS</u> <u>Chrysotile:</u> In progress <u>CSM-PLM w/ HLS</u> <u>Chrysotile:</u> 0.016-0.018% 63 bundles 592,000 bundles p/g

	Photo	Container ID	Sender	Source	Vintage	Asbestos TEM	Asbestos PLM
7		M70859-007	P2	JBP – From client Chris Powell (P2) Retailer: direct from J&J UK office/factory	2002	<6,860 s/g	<u>Blount PLM w/ HLS:</u> NAD <u>ISO PLM w/o HLS</u> <u>Chrysotile:</u> In progress <u>CSM-PLM w/ HLS</u> <u>Chrysotile:</u> 0.016-0.018% 71 bundles 691,000 bundles p/g
8		M70859-008	P2	JBP – From client Chris Powell (P2) Retailer: direct from J&J UK office/factory	2002	<6,800 s/g	<u>Blount PLM w/ HLS:</u> NAD <u>ISO PLM w/o HLS</u> <u>Chrysotile:</u> In progress <u>CSM-PLM w/ HLS</u> <u>Chrysotile:</u> 0.018-0.020% 70 bundles 1,070,000 bundles p/g
9		M70859-009	P2	JBP – From client Chris Powell (P2) Retailer: direct from J&J UK office/factory	2002	<7,130 s/g	<u>Blount PLM w/ HLS:</u> NAD <u>ISO PLM w/o HLS</u> <u>Chrysotile:</u> In progress <u>CSM-PLM w/ HLS</u> <u>Chrysotile:</u> 0.015-0.016% 59 bundles 486,000 bundles p/g

Results	UK	Chinese	JBP Total	All Total
MAS	9/9 = 100%	9/9 = 100%	9/9 = 100%	9/9 = 100%

TABLE VIII – CONTAINERS FROM OUTSIDE J&J ARCHIVE - ARGENTINA (BRAZIL)

	Photo	Container ID	Sender	Source	Vintage	Asbestos TEM	Asbestos PLM
1		M71228-001	Kelly Uustal	JBP – Off the shelf Retailer: Farmacia Botanica in Argentina	2017	NAD	Blount PLM w/ HLS: NAD ISO PLM w/o HLS Chrysotile: 0.016-0.017% 53 bundles 567,000 bundles p/g CSM-PLM w/ HLS Chrysotile: 0.005-0.006% 70 bundles 749,000 bundles p/g
2		M71228-002	Kelly Uustal	JBP – Off the shelf Retailer: Super Clin in Argentina	2017	NAD	Blount PLM w/ HLS: NAD ISO PLM w/o HLS Chrysotile: 0.009-0.012% 33 bundles 353,100 bundles p/g CSM-PLM w/ HLS Chrysotile: 0.003% 48 bundles 514,000 bundles p/g

	Photo	Container ID	Sender	Source	Vintage	Asbestos TEM	Asbestos PLM
3		M71228-003	Kelly Uustal	JBP – Off the shelf Retailer: Super Clin in Argentina	2017	NAD	<u>Blount PLM w/ HLS:</u> NAD <u>ISO PLM w/o HLS</u> <u>Chrysotile:</u> 0.016-0.017% 39 bundles 464,000 bundles p/g <u>CSM-PLM w/ HLS</u> <u>Chrysotile:</u> 0.004% 63 bundles 613,000 bundles p/g

Results	Brazil	JBP Total	All Total
MAS	3/3 = 100%	3/3 = 100%	3/3 = 100%

TABLE IX – IMERYS MDL SAMPLES

	Description	Container ID	MAS Sample ID	Sender	Vintage	Asbestos TEM	Asbestos PLM
1	West Windsor Grade 66	2018-0314-03 Imerys	M69751-037	Beasley (MDL)	1989	59,000 s/g	ISO: <0.1 Tre/Act
							Blount: <0.7 Tre/Act
2		2018-0343-03A Imerys	M69757-005	Beasley (MDL)	1990	27,000 s/g Anthophyllite Average Aspect Ratio: 11.1	ISO: <0.1 Tre/Act <0.1 Anth
							Blount: <0.1 Tre/Act <0.1 Anth
3		2018-0358-01A Imerys	M69757-007	Beasley (MDL)	1990	39,000 s/g Anthophyllite Actinolite Average Aspect Ratio: 11.1	ISO: <0.1 Tre/Act
							Blount: <0.1 Tre/Act <0.1 Anth
4	West Windsor Grade 66	2018-0320-01A Imerys	M69751-039	Beasley (MDL)	1991	NAD	NAD
5	West Windsor Grade 96	2018-0320-13A Imerys	M69751-040	Beasley (MDL)	1991-1992	13,000 s/g Anthophyllite Average Aspect Ratio: 11.1	ISO: NAD
							Blount: <0.1 Tre/Act
6		2018-0339-05 Imerys	M69757-004	Beasley (MDL)	1994	NAD	NAD
7	West Windsor Grade 66	2018-0313-02A Imerys	M69751-036	Beasley (MDL)	1995	4,400 s/g Tremolite Average Aspect Ratio: 35.0	NAD

	Description	Container ID	MAS Sample ID	Sender	Vintage	Asbestos TEM	Asbestos PLM
8		2018-0344-04A Imerys	M69757-006	Beasley (MDL)	1996	NAD	NAD
9	Railcar & Bag Sample Grade 66	2018-0315-021A Imerys	M69751-002	Beasley (MDL)	1999	NAD	NAD
10	Railcar & Bag Sample West Windsor Grade 66	2018-0315-01A Imerys	M69751-001	Beasley (MDL)	2001-2002	4,400 s/g Tremolite Average Aspect Ratio: 8.8	NAD
11	Railcar & Bag Sample West Windsor Float Feed	2018-0316-020A Imerys	M69751-006	Beasley (MDL)	Dec 2000	4,600 s/g Tremolite Average Aspect Ratio: 35.0	ISO: NAD Blount: <0.1 Tre/Act
12	Railcar & Bag Sample West Windsor Float Feed	2018-0316-021A Imerys	M69751-007	Beasley (MDL)	Feb 2000	8,700 s/g Tremolite Average Aspect Ratio: 12.2	NAD
13	West Windsor Grade 66	2018-0317-04A Imerys	M69751-038	Beasley (MDL)	2000	NAD	NAD
14	Railcar & Bag Sample Silo Grade 66	2018-0315-040A Imerys	M69751-004	Beasley (MDL)	2001	NAD	NAD
15	Railcar & Bag Sample West Windsor Float Feed	2018-0316-022A Imerys	M69751-008	Beasley (MDL)	Jan 2003	NAD	NAD

Results	**All Total**
MAS	8/15 = 53%

TABLE X – SUPRA H CHINESE TALC RETAINS

	Description	MAS Sample ID	BV/RJLG Sample ID	Imerys Ore Lot	Sender	Asbestos TEM	Asbestos PLM
1	Mill Guangxi Solid Sample	M71109-001	BV No. A5152004-006A		Imerys Mine Segrave (SGP)	NAD	PLM w/o HLS Chrysotile: 0.007-0.01% Blount PLM w/ HLS Trem/Act: NAD CSM-PLM w/ HLS Chrysotile: 0.001-0.002%
2	Guangxi/crude Solid/loose powder	M71110-001	RJLG No. 3136120		Imerys Mine Sanchez (SGP)	NAD	PLM w/o HLS Chrysotile: 0.008-0.01% Blount PLM w/ HLS Trem/Act: NAD CSM-PLM w/ HLS Chrysotile: 0.001-0.002%
3	Mill Guangxi loose powder	M71111-001	RJLG No. 3138491	MVN C01315C2	J&J Retain (SGP)	NAD	PLM w/o HLS Chrysotile: 0.006-0.008% Blount PLM w/ HLS Trem/Act: NAD CSM-PLM w/ HLS Chrysotile: 0.0010-0.0013%
4	Mill Guangxi loose powder	M71111-002	RJLG No. 313455	MVN C01315C2	J&J Retain (SGP)	NAD	PLM w/o HLS Chrysotile: 0.007-0.01% Blount PLM w/ HLS Trem/Act: NAD CSM-PLM w/ HLS Chrysotile: 0.0010-0.0013%

	Description	MAS Sample ID	BV/RJLG Sample ID	Imerys Ore Lot	Sender	Asbestos TEM	Asbestos PLM
5	Mill Guangxi loose powder	M71111-003	RJLG No. 3140762	MVN C01315C2	J&J Retain (SGP)	NAD	PLM w/o HLS Chrysotile: 0.007-0.009% Blount PLM w/ HLS Trem/Act: NAD CSM-PLM w/ HLS Chrysotile: 0.0010-0.0014%
6	Mill Guangxi loose powder	M71111-004	RJLG No. 3141790	MVN S0246C2	J&J Retain (SGP)	NAD	PLM w/o HLS Chrysotile: 0.005-0.007% Blount PLM w/ HLS Trem/Act: NAD CSM-PLM w/ HLS Chrysotile: 0.0008-0.0011%
7	Mill Guangxi loose powder	M71111-005	RJLG No. 3143083	MVN S0246C2	J&J Retain (SGP)	NAD	PLM w/o HLS Chrysotile: 0.006-0.008% Blount PLM w/ HLS Trem/Act: NAD CSM-PLM w/ HLS Chrysotile: 0.0010-0.0013%
8	Mill Guangxi loose powder	M71111-006	RJLG No. 3144312	MVN S0246C2	J&J Retain (SGP)	NAD	PLM w/o HLS Chrysotile: 0.007-0.01% Blount PLM w/ HLS Trem/Act: NAD CSM-PLM w/ HLS Chrysotile: 0.0011-0.0012%

	Description	MAS Sample ID	BV/RJLG Sample ID	Imerys Ore Lot	Sender	Asbestos TEM	Asbestos PLM
9	Mill Guangxi loose powder	M71111-007	RJLG No. 3145361	MVN S0246C2	J&J Retain (SGP)	NAD	PLM w/o HLS Chrysotile: 0.007-0.009% Blount PLM w/ HLS Trem/Act: NAD CSM-PLM w/ HLS Chrysotile: 0.0013-0.0022%
10	Mill Guangxi loose powder	M71111-008	RJLG No. 3147067	MVN S0246C2	J&J Retain (SGP)	NAD	PLM w/o HLS Chrysotile: 0.007-0.009% Blount PLM w/ HLS Trem/Act: NAD CSM-PLM w/ HLS Chrysotile: 0.0010-0.0013%
11	Mill Guangxi loose powder	M71111-009	RJLG No. 3149010	MVN S0246C2	J&J Retain (SGP)	NAD	PLM w/o HLS Chrysotile: 0.006-0.008% Blount PLM w/ HLS Trem/Act: NAD CSM-PLM w/ HLS Chrysotile: 0.0013-0.0015%
12	Supra H RM-04/17/2012 87672	M71179-001	BV A1810394-001C	H04022-76	Chanel Retain (SGP)	N/A	PLM w/o HLS Chrysotile: 0.008-0.01% CSM-PLM w/ HLS Chrysotile: 0.002-0.003%
13	Supra H RM-04/03/2012 87496	M71179-002	BV A1810394-002C	H12121-76	Chanel Retain (SGP)	N/A	PLM w/o HLS Chrysotile: 0.009-0.01% CSM-PLM w/ HLS Chrysotile: 0.002-0.003%

	Description	MAS Sample ID	BV/RJLG Sample ID	Imerys Ore Lot	Sender	Asbestos TEM	Asbestos PLM
14	Supra H RM-03/09/2011 81621	M71179-003	BV A1810394-003C	H11239-76	Chanel Retain (SGP)	N/A	PLM w/o HLS Chrysotile: 0.009-0.02% CSM-PLM w/ HLS Chrysotile: 0.002-0.005%
15	Supra H RM-03/09/2011 81615	M71179-004	BV A1810394-004C	H11230-76	Chanel Retain (SGP)	N/A	PLM w/o HLS Chrysotile: 0.009-0.02% CSM-PLM w/ HLS Chrysotile: 0.002-0.005%
16	Supra H RM-03/09/11 81628	M71179-005	BV A1810394-005C	H08240-76	Chanel Retain (SGP)	N/A	PLM w/o HLS Chrysotile: 0.008-0.01% CSM-PLM w/ HLS Chrysotile: 0.002-0.004%
17	Supra H RM-03/09/2011 81622	M71179-006	BV A1810394-006C	H06250-76	Chanel Retain (SGP)	N/A	PLM w/o HLS Chrysotile: 0.009-0.015% CSM-PLM w/ HLS Chrysotile: 0.002-0.004%
18	Supra H RM-09/20/2013 94513	M71179-007	BV A1810394-007C	H05191-76	Chanel Retain (SGP)	N/A	PLM w/o HLS Chrysotile: 0.007-0.01% CSM-PLM w/ HLS Chrysotile: 0.001-0.002%
19	Supra H RM-01/25/2010 74696	M71179-008	BV A1810394-008C	H11239-76	Chanel Retain (SGP)	N/A	PLM w/o HLS Chrysotile: 0.007-0.01% CSM-PLM w/ HLS Chrysotile: 0.001-0.002%
20	Supra H RM-08/12/2010 78525	M71179-009	BV A1810394-009C	H03270-76	Chanel Retain (SGP)	N/A	PLM w/o HLS Chrysotile: 0.008-0.01% CSM-PLM w/ HLS Chrysotile: 0.001-0.002%

	Description	MAS Sample ID	BV/RJLG Sample ID	Imerys Ore Lot	Sender	Asbestos TEM	Asbestos PLM
21	Supra H RM-01/04/2011 80529	M71179-010	BV A1810394-010C	H10130-76	Chanel Retain (SGP)	N/A	PLM w/o HLS Chrysotile: 0.007-0.01% CSM-PLM w/ HLS Chrysotile: 0.001-0.002%
22	Supra H RM-03/08/2011 81605	M71179-011	BV A1810394-011C	H01211-76	Chanel Retain (SGP)	N/A	PLM w/o HLS Chrysotile: 0.008-0.01% CSM-PLM w/ HLS Chrysotile: 0.002-0.003%
23	Supra H RM-05/24/2011 82777	M71179-012	BV A1810394-012C	H01281-76	Chanel Retain (SGP)	N/A	PLM w/o HLS Chrysotile: 0.007-0.01% CSM-PLM w/ HLS Chrysotile: 0.001-0.002%
24	Supra H RM-10/26/2011 85213	M71179-013	BV A1810394-013C	H06031-76	Chanel Retain (SGP)	N/A	PLM w/o HLS Chrysotile: 0.008-0.01% CSM-PLM w/ HLS Chrysotile: 0.002%
25	Supra H RM-04/03/2012 87497	M71179-014	BV A1810394-014C	H11231-76	Chanel Retain (SGP)	N/A	PLM w/o HLS Chrysotile: 0.007-0.01% CSM-PLM w/ HLS Chrysotile: 0.003%
26	Supra H RM-09/24/2012 89752	M71179-015	BV A1810394-015C	H08022-76	Chanel Retain (SGP)	N/A	PLM w/o HLS Chrysotile: 0.008-0.01% CSM-PLM w/ HLS Chrysotile: 0.001-0.002%
27	Supra H RM-12/21/2012 90871	M71179-016	BV A1810394-016C	H11082-76	Chanel Retain (SGP)	N/A	PLM w/o HLS Chrysotile: 0.008-0.01% CSM-PLM w/ HLS Chrysotile: 0.001%

	Description	MAS Sample ID	BV/RJLG Sample ID	Imerys Ore Lot	Sender	Asbestos TEM	Asbestos PLM
28	Supra H RM-09/09/2013 94514	M71179-017	BV A1810394-017C	H04223-76	Chanel Retain (SGP)	N/A	PLM w/o HLS Chrysotile: 0.009-0.01% CSM-PLM w/ HLS Chrysotile: 0.001-0.002%
29	Supra H RM-05/20/2012 92890	M71179-018	BV A1810394-018C	H04223-76	Chanel Retain (SGP)	N/A	PLM w/o HLS Chrysotile: 0.007-0.009% CSM-PLM w/ HLS Chrysotile: 0.001%

Results	**All Total – Supra H Chinese Talc Ores**
MAS	29/29 = 100%

SUMMARY TABLES

TABLE I – CONTAINERS FROM OUTSIDE J&J ARCHIVE PRE 2003 U.S. (ITALIAN & VERMONT)

Results	Italian	Vermont	JBP Total	STS Total	All Total
MAS	11/18 = 61%	4/4 = 100%	15/22 = 68%	N/A	15/22 = 68%

TABLE II – CONTAINERS FROM OUTSIDE J&J ARCHIVE POST 2003 U.S. (CHINESE)

Results	Chinese	JBP Total	STS Total	All Total
MAS	37/40 = 93%	36/39 = 92%	1/1 = 100%	37/40 = 93%

TABLE III – VALEANT CONTAINERS FROM OUTSIDE J&J ARCHIVE POST 2003 (CHINESE)

Results	Chinese	STS Total	All Total
MAS	2/3 = 67%	2/3 = 67%	2/3 = 67%

TABLE IV – J&J ARCHIVE CONTAINERS (U.S.)

Results	Italian	Vermont	JBP	STS	All Total
MAS	7/14 = 50%	29/36 = 81%	18/27 = 67%	18/23 = 78%	36/50 = 72%

TABLE V – J&J ARCHIVE CONTAINERS (ASIA)

Results	Asian	JBP Total	STS Total	All Total
MAS	7/9 = 78%	7/9 = 78%	N/A	7/9 = 78%

TABLE VI – J&J ARCHIVE CONTAINERS (U.K. and AUSTRALIA)

Results	U.K.	Australia	JBP Total	STS Total	All Total
MAS	7/11 = 64%	2/2 = 100%	8/12 = 67%	1/1 = 100%	9/13 = 69%

TABLE VII – CONTAINERS FROM OUTSIDE J&J ARCHIVE – UNITED KINGDOM

Results	UK	Chinese	JBP Total	All Total
MAS	9/9 = 100%	9/9 = 100%	9/9 = 100%	9/9 = 100%

TABLE VIII – CONTAINERS FROM OUTSIDE J&J ARCHIVE - ARGENTINA (BRAZIL)

Results	Brazil	JBP Total	All Total
MAS	3/3 = 100%	3/3 = 100%	3/3 = 100%

TABLE IX – IMERYS MDL

Results	All Total
MAS	8/15 = 53%

TABLE X – SUPRA H CHINESE TALC RETAINS

Results	All Total – Supra H Chinese Talc Ores
MAS	29/29 = 100%

COMBINED U.S. CONTAINER ORE SUMMARY (W/OUT VALEANT STS, IMERYS MDL ORE, and CHINESE RETAINS)

Italian Ore (U.S.)	Vermont Ore (U.S.)	Chinese Ore (U.S.)	JBP Total Containers (U.S.)	STS Total Containers (U.S.)	Total U.S. Containers
18/32 = 56%	33/40 = 83%	37/40 = 93%	69/88 = 78%	19/24 = 79%	88/112 = 79%

COMBINED ALL CONTAINER SUMMARY (W/OUT VALEANT STS, IMERYS MDL ORE, and CHINESE RETAINS)

U.S. Containers	U.K. Containers	Australia Containers	Asia Containers	Argentina Containers	JBP Total Containers	STS Total Containers	All Total Containers
88/112 = 79%	16/20 = 80%	2/2 = 100%	7/9 = 78%	3/3 = 100%	96/121 = 79%	20/25 = 80%	116/146 = 79%

COMBINED ALL U.S. CHINESE ORE SUMMARY

U.S. Containers	JBP Containers	JNJ STS Containers	Valeant STS Containers	Guang Xi/Supra H Ores	All Chinese Ore Total
39/43 = 91%	45/48 = 94%	1/1 = 100%	2/3 = 67%	29/29 = 100%	77/81 = 95%

Exhibit E

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MAS Project 14-1852
Below the Waist Application of
Johnson & Johnson Baby Powder

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Supplemental Report #2
January 2018

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Index of Supplemental Data

Data	Explanation of Changes
1-11-2018	Sec. 6 - De-colorized and reformatted bench sheets to include footer
1-15-2018	Sec. 6 - Added additional images to samples that had optical artifacts present
1-15-2018	Sec. 3 - Summary Table updated to include additional sample analyses
1-16-2018	Sec. 6 - Original and Supplemental MAS COC redacted to reflect analyses
1-16-2018	Sec. 6 - Additional sample analysis added to data set
3-8-2018	Updated Cover and TOC with Revision 2 and date, Updated summary tables in Section 3, Added 7402 Analysis to Section 6, Added TEM Level II Analysis & <3:1 Ratios Counts to Section 7, Moved Photos to Section 8

MAS Project No. 14-1852
Below the Waist
Application of Johnson & Johnson Baby Powder

Supplemental Report #2
March 2018

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7	TEM Level II Analysis of M67341-005 TEM 7402 Analysis of M67341 of Aspect Ratio <3:1
8	Photographs of Johnson & Johnson Baby Powder Can M65205-001

Section 1

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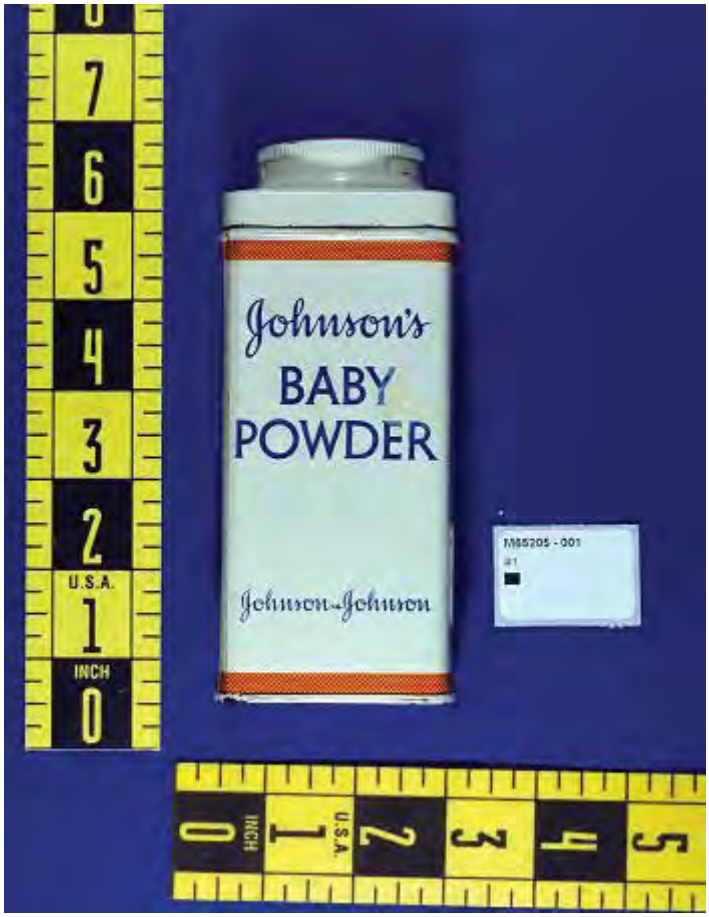
MAS Project 14-1852
Below the Waist Application of Johnson & Johnson Baby Powder
Supplemental Expert Report #2



William E. Longo, Ph.D
Mark W. Rigler, Ph.D
William B. Egeland, M.S., P.G.
Materials Analytical Services, LLC
March, 2018

Overview

This report describes the procedures and methodology used to analyze for airborne asbestos amphibole fiber exposure during the application of talc-containing Johnson's Baby Powder metal container M65205-001. Previous bulk ATEM analysis of the Johnson's Baby Powder from this can showed a tremolite concentration of 15,100,000 tremolite fibers.

Approximately 4 grams of baby powder were applied to the lower body of an investigator to determine the potential exposure levels of an individual to asbestos amphibole fibers while applying Johnson's Baby Powder. Both the NIOSH 7400 PCM method and the NIOSH 7402 TEM method were performed to determine if any detectable amphibole asbestos fibers from the Johnson's Baby Powder were released into the breathing zone of the investigator and immediate surrounding area in the ECL. The Johnson's Baby Powder application procedure used in this study was based on the testimony of the plaintiff, Jody Ratcliff.

The NIOSH 7400 PCM analysis found that the four personal sample results ranged from 3.85 f/cc to 5.86 f/cc with an average mean of 4.52 f/cc. Area air sample results were 0.28 f/cc to 0.58 f/cc with an average mean of 0.41 f/cc.

Four of the personal PCM filters were analyzed by the NIOSH 7402 TEM method and the percent tremolite asbestos fiber concentration ranged from 42.9% to 76.9% resulting in a PCM equivalent range of 1.81 f/cc to 4.51 f/cc.

Fibrous Talc

In addition to airborne tremolite asbestos fiber/cc measurements, the NIOSH 7402 TEM method was used to quantitate the airborne fibrous talc concentrations in each of the four personal air samples. The airborne fibrous talc concentrations ranged from 0.45 f/cc to 1.86 f/cc with an average mean of 1.23 f/cc.

Materials and Methods

The metal Johnson's Baby Powder talc container (M65205-001) that was used for this exposure study was received at MAS on September 15, 2016 and bulk ATEM analysis was done in February of 2017. The sample has been in locked archive at MAS until this IH study was performed. Photographs of the Johnson's Baby Powder bottle can be found in Section 7.

Sample Preparation

Immediately prior to performing the study, the received Johnson's Baby Powder talc sample was removed from archive and the container was weighed on a Fisher Scientific balance and the weight recorded. The total weight of the bottle and powder was 117.7g. Immediately after the study was performed, the container of baby powder was again weighed. The total weight of the

bottle and powder after the study was 113.65g. Total weight during the application process was 4.05g.

Application Study Protocol

A description of the exposure characterization lab (ECL) and what was done during the study can be found in Section 2 - Protocol of this study.

A 15'x15'x8' room with appropriate negative asbestos airflow technology was used. Three Tyndall lights as well as standard lights were present in order to be able to alternate between the two types of lighting. Two Sony Model HDR-CX900 video cameras were stationed at viewing ports on two sides of the ECL. Four high-volume area sampling pump stations were set up at a distance of 5' to 6' from the investigator using 25mm air cassettes containing 0.8µm pore size mixed cellulose ester (MCE) filters with 5.0µm backing pads. Those pumps were calibrated to run at 10 liters/minute and both background samples and areas samples were pulled from these stations. Four additional low-volume "personal" pumps were affixed to the investigator with the cassettes adjusted to be in the breathing zone of the investigator. Those pumps were calibrated to 2.5 liters/minute. A chair was placed in the center of the ECL on which the investigator sat.

Attempting to follow the deposition of the plaintiff (Jody Ratcliff) as closely as modesty allowed, the investigator wore only an inner pair of boxer briefs covered by an outer pair of bikini briefs. The investigator sat in the chair in the middle of the ECL while holding the metal can of Johnson's Baby Powder. The investigator performed two shakes into his hand and then rubbed that powder onto one upper leg area. The investigator then performed the same two shakes of the Johnson's Baby Powder container and applied the baby powder to the other upper leg. Next, the investigator stood, pulling the bikini brief down and out in the front, and applied the baby powder product with two squeezes into the crotch area of the bikini briefs. The investigator then released the briefs and sat back down in the plastic chair. The investigator remained sitting until a total of five minutes was reached.

PCM Fiber Analysis Procedure

An Olympus CX21 optical microscope equipped with appropriate phase contrast oculars and objectives for NIOSH 7400 analyses was used for the PCM analyses. NIOSH 7400 "A" counting rules were followed.

NIOSH 7402 TEM Method

JEOL 1200EX TEM equipped with an energy dispersive x-ray analyzer (EDXA) was employed for this analysis. The air samples were analyzed at a screen magnification of 1000X. Amphibole fibers or bundles with substantially parallel sides and an aspect ratio of 3:1 or greater, at least

longer than 5.0 µm in length and greater than 0.25 µm were counted as per NIOSH 7402 asbestos structure sizing rules. Positive identification of amphibole asbestos requires EDXA for mineral chemistry conformation and selected area electron diffraction (SAED) for each amphibole type. However, at times, an amphibole bundle may have a diameter that is too thick to acquire a SAED pattern, then only the mineral chemistry can be used.

Additionally, the personal and area air samples were reanalyzed for any tremolite structures that were less than 5.0 in length. This would include tremolite structures less than 3:1 aspect ratios.

Fibrous Talc Analysis

The four personal air samples were also analyzed by the NIOSH 7402 method for the amount of fibrous talc particles that were also present in the breathing zone of the investigator during the study.

Results

The results of both the PCM 7400 and TEM 7402 analyses for the study are shown in Table 1 and fully summarized in Section 3. Specific results for both the PCM and TEM analyses can be found in Sections 5 and 6 of this report.

Table 1
Johnson's Baby Powder
PCM & TEM Airborne Tremolite & Talc Fiber Exposure Levels

Sample ID	No. of Air Samples Analyzed	PCM Range & Mean F/cc	7402 TEM Tremolite Percent	PCME Range & Mean Tremolite F/cc	7402 TEM Range & Mean Talc F/cc
Background (BG-1-A,B,C,D)	4	<0.002 Mean <0.002	0%	<0.002	<0.002
Worker (P-1-A,B,C,D)	4	3.85 to 5.86 4.52	43% to 77%	1.81 to 4.51 2.57	1.78 to 2.50 1.95
Area (A-1-A,B,C,D)	4	0.28 to 0.58 0.41	30.8 to 71.4	0.13 to 0.31 0.2	.08 to 0.29 .19

All the analytical data and photographs can be found in Sections 5, 6 & 7 of this report. This data includes sample PCM and TEM count sheets, EDXA spectra, SAED micrographs and

representative photo-micrographs of the fibrous amphiboles found. Photographs of the Johnson's Baby Powder container associated with this study is also provided in Section 6 of this report.

Discussion and Conclusions

Jody Ratcliff testified in her deposition that she would, at times, apply Johnson's Baby Powder while sitting on her bed to both her legs after shaving and then in her underwear/groin area after she stood up. This hygiene study substantially replicated her Johnson's Baby Powder application process as shown in the MAS video that was recorded during this study.

The four personal air samples that were collected in the breathing zone of the investigator showed an average mean tremolite asbestos fiber exposure of 2.57 f/cc and an average mean fibrous talc exposure of 1.95 f/cc.

These results show that an individual, such as Jody Ratcliff, who uses asbestos-containing Johnson's talcum powder, can have a significant exposure to airborne amphibole fibers as shown in this study. The magnitude of the asbestos fiber exposure levels will depend on the concentration level of the naturally occurring asbestos in the Johnson's Baby Powder product.

In addition to the fibrous tremolite exposures, our study showed that there was significant exposure to asbestiform talc fibers from the application of the Johnson's Baby Powder during the study.

Sections 2-8

The remainder of this report is some 850 pages. In light of its size, only relevant excerpts have been included here. The entire report will be produced upon request.

As a courtesy, all defendants have been served with Dr. Longo's entire report.

Section 2

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MAS PROJECT 14-1852
BELOW THE WAIST APPLICATION OF
JOHNSON and JOHNSON BABY POWDER

Application Study
September 6, 2017

Protocol

I. ECL SET-UP

A. Study is to be performed in the exposure characterization lab (ECL) constructed using negative airflow asbestos abatement technology. The internal space of the ECL was reduced to 15' x 15' x 8' to simulate the approximate size of the plaintiff's bedroom. The ECL will be decontaminated before the study.

B. Air exchange inside the ECL will be approximately 14 cubic feet per minute to simulate a typical residential ventilation rate of 0.5 ACH as measured 10 feet (at center of 12" ID duct) from the air exhaust of the HEPA filter negative air machine.

C. Tyndall lighting set up in general accordance with the methods described in D.T. Chambers, "Asbestos", John Wiley & Sons, 6, 193, 1983 and the Environmental Protection Agency SOP, EPA-Libby-02, Revision #1, March 2001. The lighting source will be three high intensity lights (1000 watts, ellipsoid Pyrex glass lens, 219K candle power, and 8 degree beam angle) located on each side of the work activity at a height of approximately 5.5 feet from the floor and between 4 to 6 feet from the work activity.

D. Two video cameras (Sony Model HDR-CX900) will be used in this study.

II. BACKGROUND AIR SAMPLES

A. Adjust and calibrate high volume area pumps to approximately 10 liters per minute.

B. Set up four area air samples, one in each quadrant of the ECL. Use 25mm air cassettes containing 0.8µm pore size mixed cellulose ester (MCE) filters with 5.0µm backing pads.

C. Locate the area air samples in each quadrant of the ECL at a height of 55 inches from the floor and a distance of approximately 5 to 6 feet from the application activity.

III. APPLICATION STUDY

A. The investigator will wear a supplied air respirator during the study.

B. The weight of the Johnson & Johnson Baby Powder can (M65205-001) and powder will be weighed prior to the investigation. The investigator will wear only an inner pair of boxer briefs covered by an outer pair of bikini briefs. The investigator will sit in a plastic chair in the middle of the ECL while holding the metal can of Johnson & Johnson Baby Powder (M65205-1). The investigator will first perform two shakes of the can of baby powder into his hand and then rub the talcum powder onto one upper leg area. He will then perform the same two shakes of the can and apply the baby powder to the other upper leg. Next, the investigator will stand, pulling the waist band of the bikini briefs down and out in the front, then apply the baby powder product with two squeezes into the crotch area of the bikini briefs. The investigator will then release the briefs and sit back down in the chair.

C. The investigator will remain sitting still until the 5 minute mark is reached at which time the study is concluded and the air sampling pumps are turned off.

D. The investigator will wear four personal air pumps and air cassettes located in the breathing zone and calibrated at a flow rate of 2.5 liters per minute.

E. The application practice will be performed under both ambient and Tyndall lighting. The entire procedure will be recorded by two separate cameras.

F. While recording during the study, Tyndall lighting will be turned on several times and overhead lights turned off.

G. Area air samples will be taken during the study in each quadrant of the ECL and calibrated at a flow rate of approximately 10 liters per minute.

H. Two field blanks will be opened inside the ECL after the study has been completed. The Johnson & Johnson Baby Powder can and powder will again be weighed after the investigation.

IV. Laboratory Analysis

All air samples will be analyzed by the NIOSH 7400 PCM method using “A” counting rules. After a portion of the filter has been removed for the PCM analysis, selected air filter samples will be analyzed by the NIOSH 7402 method using TEM.

Section 3

MAS

SUMMARY OF RESULTS

Below the Waist Application of Johnson & Johnson Baby Powder
An Application Study

M67341
BACKGROUND SAMPLES

Sample #	Sample Location	PCM Fibers/cc	TEM (7402) %Asbestos	ASB PCME Fibers/cc	TEM (7402) %Talc	Talc PCME Fibers/cc
M67341-001 **BG-1-A**	Background Inside ECL (NE)	<0.002	0	<0.002	0	<0.002
M67341-002 **BG-1-B**	Background Inside ECL (SE)	<0.002	0	<0.002	0	<0.002
M67341-003 **BG-1-C**	Background Inside ECL (SW)	<0.002	0	<0.002	0	<0.002
M67341-004 **BG-1-D**	Background Inside ECL (NW)	<0.002	0	<0.002	0	<0.002

PERSONAL SAMPLES

Sample #	Sample Description	PCM Fibers/cc	TEM (7402) % Asbestos	ASB PCME Fibers/cc	TEM (7402) %Talc	Talc PCME Fibers/cc
M67341-005 **P-1-A**	Worker (Right Shoulder)	5.86	76.9	4.51	23.1	1.35
M67341-006 **P-1-B**	Worker (Right Shoulder)	4.38	42.9	1.88	57.1	2.50
M67341-007 **P-1-C**	Worker (Left Shoulder)	3.85	53.8	2.07	46.2	1.78
M67341-008 **P-1-D**	Worker (Left Shoulder)	3.98	45.5	1.81	54.5	2.16

AREA SAMPLES

Sample #	Sample Description	PCM Fibers/cc	TEM (7402) % Asbestos	ASB PCME Fibers/cc	TEM (7402) %Talc	Talc PCME Fibers/cc
M67341-009 **A-1-A**	Area Inside ECL NE	0.52	58.8	0.31	41.2	0.13
M67341-010 **A-1-B**	Area Inside ECL SE	0.28	71.4	0.20	28.6	0.08
M67341-011 **A-1-C**	Area Inside ECL SW	0.42	30.8	0.13	69.2	0.29
M67341-012 **A-1-D**	Area Inside ECL NW	0.40	40.0	0.16	60.0	0.24

FIELD BLANKS

Sample #	Sample Description	PCM Fibers/mm^2	TEM (7402) % Asbestos
M67341-014 **FB-1-A**	Field Blank	<7	0
M67341-015 **FB-1-B**	Field Blank	<7	0

Exhibit F

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DECLARATION OF ANTHONY M. HERNANDEZ VALADEZ

I, Anthony M. Hernandez Valadez, declare:

1. I am an adult over the age of 18 years and have personal knowledge of the facts expressed in this declaration. If asked, I could and would testify to the truth of such facts.

2. I am 23 years old and have been a lifelong resident of California.

3. In January 2022, I was diagnosed with mesothelioma. After subsequent scans, it is my understanding that my doctors have determined that I have pericardial mesothelioma.

4. I was born on September 23, 1998. When I was a baby, it is my understanding that my mother regularly used Johnson's Baby Powder talc on me, including during diaper changes and whenever it was needed. My mother and other family members continued using Johnson's Baby Powder talc on me throughout my childhood as part of my regular hygiene routine.

5. I first used Johnson's Baby Powder talc on myself when I was around 13 years old. I continued using that product for several years thereafter. During that time, I used a lot of Johnson's Baby Powder talc throughout my body, including on my chest, armpits, private areas, back, and neck. I used Johnson's Baby Powder talc every day, multiple times each day, including after showers, before going out, or whenever I need to freshen up. I applied that product either directly from the bottle or with my hands. It took me at least a couple of minutes to apply the powder. I used Johnson's Baby Powder talc because it was effective in combating sweat and odors. I also liked the product's fresh smell. Johnson & Johnson was a brand that I trusted.

6. Johnson & Johnson never warned me about its talc baby powder's asbestos content or asbestos-related health hazards, including cancer. If Johnson & Johnson warned me of such hazards, I would have never used its talc baby powder.

7. I do not recall any circumstance in which I or anyone in my household would have been in or around any dusty environments other than through my use of Johnson's Baby Powder. Before my diagnosis, I worked part-time as a customer service representative at Home Depot earning $15 per hour. At that job, I only helped customers buy doors and windows. I did not do any hands-on work with any tools, products, or any other machinery. Nor was I ever around any dusty environment. Prior to Home Depot, I was a customer service representative at Target and

did no hands-on work with any tools, products, or any other machinery. For most of my life, my mother stayed at home to raise and care for me and my brother. Afterwards, my mom did yard duty and office work at a school. She currently works an office job at the local cemetery. My biological father died when I was four years old and I do not recall any interactions with him. My mother's current husband is a residential gardener who mows lawns and does landscaping. I never saw any dust on the work clothes of my mother or her current husband. I have never lived in or near any industrial areas or dust-generating facilities.

8. Prior to my mesothelioma diagnosis, I was an outgoing person who loved spending time with friends and family. For example, my friends and I often went out for dinner or lunch. I also enjoyed working and often worked overtime because of the camaraderie and several of my friends worked with me. I also enjoyed creative writing. Before my diagnosis, I was attending classes at Merced Community College and was only three semesters away from completing my Associates Degree. After obtaining that degree, I intended to transfer to a university in Southern California to major in criminology in the hopes of working in law enforcement or as a private investigator.

9. Having mesothelioma is the worst thing that has ever happened to me. I never had a serious, let alone life threatening, illness prior to my mesothelioma diagnosis. Mentally, this illness has caused me great anxiety and depression. Talking about my current state makes my heart race to the point where I am having a panic attack. I refuse to communicate with any of my friends and family because I am in disbelief and shock that I am suffering from a terminal disease at such a young age. Physically, this disease and any treatments related to it, including chemotherapy and cardiac surgery on February 17, 2022, have caused me to experience nausea/vomiting, loss of appetite, severe chest pain and tightness, shortness of breath, discomfort, fatigue, and chronic back pain. I have been admitted to the emergency department several times since my diagnosis, the most recent of which occurred on April 4, 2022, because of complications related to my first round of chemotherapy. It is my understanding that I have several rounds to go and greatly fear that I will not tolerate any of them.

10. I understand that this disease is terminal. No words can express my sadness in

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knowing that this disease has foreclosed me from the opportunity of realizing my hopes and dreams. I am very scared of what will happen to me.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct, and that I signed this declaration at Merced, California on April 8, 2022.

Anthony M. Hernandez Valadez

Anthony M. Hernandez Valadez

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Exhibit G

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DECLARATION OF ANNA CAMACHO

I, Anna Camacho, declare:

1. I am an adult over the age of 18 years and have personal knowledge of the facts expressed in this declaration. If asked, I could and would testify to the truth of such facts.

2. I am the mother of Anthony M. Hernandez Valadez ("Anthony"). He is the eldest of my two sons. Anthony suffers from and has been diagnosed with pericardial mesothelioma.

3. When Anthony was a baby, I regularly used a lot of Johnson's Baby Powder talc on him every day, multiple times each day, including during diaper changes, after baths, to treat or prevent diaper rash, and whenever it was needed. I packed the baby powder throughout Anthony's body, including on his private areas, arms, neck forehead, armpits, and chest. I applied the powder either directly from the bottle or with my hands. I also saw other family members apply Johnson's Baby Powder on Anthony while he was a baby.

4. Even after he was no longer wearing diapers, I continued using Johnson's Baby Powder talc on Anthony throughout his childhood. I applied that product in the same way and in the same areas that I previously mentioned in the paragraph above. In addition, I applied Johnson's Baby Powder on Anthony's feet and in between his toes, as well as inside his shoes.

5. Anthony began using Johnson's Baby Powder talc on himself when he was around 13 years old and continued using it for several years afterwards. I know that Anthony was using Johnson's Baby Powder talc because the product was in the house and I saw remnants of baby powder on Anthony's clothes and armpits. I also reminded Anthony to use Johnson's Baby Powder because it was effective in combating odors and sweat.

6. Using Johnson's Baby Powder talc on Anthony always generated dust. Anthony breathed that dust.

7. I was the person in the household who bought Johnson's Baby Powder that was used on or by Anthony. The powder was in an all-white bottle. The twist cap was also white. The name "Johnson's" in script appeared on the front of the bottle. We always had multiple bottles of Johnson's Baby Powder around the house. When Anthony was a baby, I always had a bottle of Johnson's Baby Powder in his diaper bag. I always bought the largest size of baby powder

EXHIBIT G

available. I also bought the travel size bottle. We used so much Johnson's Baby Powder that I bought it every two weeks from various retail and grocery stores, including Lucky, Safeway, Target, and Walmart. I have photographs that depict bottles of that product throughout the family home at various stages of Anthony's life. Johnson & Johnson's was a brand I trusted.

8. Johnson & Johnson and the retailers that sold its talc baby powder never warned me about the product's asbestos content or asbestos-related health hazards, including cancer. If Johnson & Johnson and the retailers warned me of such hazards, I would have never used Johnson's Baby Powder talc on me, Anthony, or his brother.

9. I do not recall any circumstance in which I or anyone in my household would have been in or around any dusty environments other than through my use of Johnson's Baby Powder. For most of Anthony's life, I was a stay-at-home mother who raised and cared for Anthony and his brother. It was not until 2007 did I start working again. In 2007, I did yard duty and office

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work at a school. I currently work an office job at the local cemetery. Anthony's father, Michael Valadez, died when Anthony was four years old. Michael did not work for pay because he was receiving aid from a federal assistance program for families with dependent children. Michael had no interaction with Anthony during Anthony's childhood. My current husband is a residential gardener who mows lawns and does landscaping. I never saw any dust on my, Michael's, or my current husband's work clothes. Anthony and I never lived in or near any industrial areas or dust-generating facilities.

10. I am in shock that Anthony has a terminal illness at such a young age. I care for Anthony every day and words cannot describe how his mesothelioma has negatively affected his mental and physical well-being. Anthony was outgoing and hardworking before his diagnosis. Now, he is suffering from anxiety and depression. He also experiences shortness of breath, extreme fatigue, and debilitating pain throughout his body. This disease has greatly traumatized me and Anthony. I highly doubt that we will ever recover from it.

11. I understand that Anthony's disease is terminal. Since his mesothelioma, Anthony has been admitted to the emergency department several times for complications related to his mesothelioma. I live in fear every day because I do not know whether today will be Anthony's last.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct, and that I signed this declaration at Merced, California on April 8, 2022.

Anna Camacho

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Exhibit 27

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Counsel for Movant Anthony Hernandez Valadez

IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF NEW JERSEY

In re:	:	Chapter 11
	:	
LTL MANAGEMENT LLC,	:	Case No. 21-30589
	:	
Debtor.	:	
	:	

DECLARATION OF LEAH MONIQUE BACKHUS, M.D., MPH, FACS

EXHIBIT 27

Pursuant to 28 U.S.C. § 1746, I, Leah Monique Backhus, M.D., MPH, FACS, declare under penalty of perjury as follows:

1. I am an adult over the age of 18 years and not a party in this case. I have personal knowledge of the facts set forth in this declaration, except for such facts that have been made known to me in forming an opinion, in which case each such fact is of a type on which professionals in my field reasonably rely in forming such opinions. The facts stated in this declaration that are within my personal knowledge are true. If asked, I could and would testify competently to the truth of and foundation for each fact and opinion asserted within this declaration

2. Attached hereto as **Exhibit A** is a copy of my current curriculum vitae, which truthfully states my qualifications to provide expert testimony in this action.

3. I received my Bachelor of Arts in Human Biology from Stanford University, my medical degree from the Keck School of Medicine at the University of Southern California, and my Masters in Public Health from the School of Public Health at the University of Washington. I completed residency training in general surgery at the University of Southern California and cardiothoracic surgery at the University of California, Los Angeles.

4. Presently, I practice at Stanford Hospital and am the Chief of Thoracic Surgery at the Veterans Administration's Health Care System in Palo Alto, California. My surgical practice consists of general thoracic surgery with special emphasis on thoracic oncology and minimally invasive surgical techniques. I am also the Co-Director of the Thoracic Surgery Clinical Research Program and have grant funding through the Veterans Affairs Administration and National Institute of Health. I am a member of the National Lung Cancer Roundtable of the American Cancer Society serving as Chair of the Task Group on Lung Cancer in Women. I also

serve on the Board of Directors of the Society of Thoracic Surgeons. As an educator, I am the Associate Program Director for the Thoracic Track Residency and served as the Chair of the Accreditation Council for Graduate Medical Education's Residency Review Committee for Thoracic Surgery from 2016-2022, which is the accrediting body for all cardiothoracic surgery training programs in the United States. I am a recipient of the annual McGoon Award for Teaching in Thoracic Surgery and the Levi Watkins Innovation and Leadership Scholarship.

5. I have reviewed and considered numerous reports in the scientific and medical literature regarding the study of asbestos-related disease. I have also made presentations regarding mesothelioma. [*See* Exh. A at pp. 24 and 25 (¶¶ 9 and 18).] My clinical focus includes treating mesothelioma patients.

6. I treated Anthony Michael Hernandez Valadez for his mesothelioma. He is 23 years old and was born on September 23, 1998.

7. On February 14, 2022, I had a history and physical ("H&P") examination as part of a consultation for Mr. Valadez. Attached hereto as **Exhibit B** is a true and correct copy of my consultation Report, dated February 14, 2022. In my report I noted that Mr. Valadez has "a history of newly diagnosed pericardial epithelioid mesothelioma [complicated by] malignant pericardial and pleural effusions and constrictive pericarditis." [Exh. B at 108.] Mr. Valadez "originally presented in 2020 with persistent cough and pericardial [effusion] that failed to respond to multiple courses of colchine and prednisone over the past 2 years." [*Id.* at 108-109.] On January 4, 2022, Mr. Valadez presented with "progressive cervical adenopathy and workup demonstrating pericardial mass, worsening pericardial effusion, and small pleural effusions." [*Id.* at 109.] Six days later, Mr. Valadez underwent a biopsy and the pathology revealed

mesothelioma, epithelioid type. [*Id.*] In February 2022, Mr. Valadez underwent a bilateral thoracentesis with removal of 1.5 liters from each side of his chest. [*Id.*]

8. When I saw him on February 14, 2022, Mr. Valadez presented with "symptomatic rapid reaccumulation of bilateral malignant pleural effusions." [Exh. B at 112.] He was persistently tachycardic, which means that his heart rate is constantly over 100 beats a minute. [*Id.* at 109.] He also had labored breathing, persistent food regurgitation, body aches, and a nonproductive cough. [*Id.*] I assessed Mr. Valadez's pericardial mesothelioma, which is an extremely rare condition with a poor prognosis. [*Id.* at 112-113.] He also has extensive adenopathy (swollen lymph nodes) which underscores the advanced stage of his pericardial mesothelioma. [*Id*.] I recommended that the primary team treating Mr. Valadez "[c]onsult to cardiac surgery." [*Id.* at 113.] I also recommended that Mr. Valadez and his family discuss initiation of chemotherapy with medical oncology, as well as to consult with cardiac surgery for consideration of pericardiectomy as means of surgical debulking and palliation of his symptoms given evidence of hemodynamically significant constrictive-effusive pericarditis. [*Id.* at 112-113.]

9. I was the surgeon who performed on Mr. Valadez a resection of mediastinal mass and thymectomy and placement of bilateral PleurX catheters. The latter of which were to treat his large pleural effusions from chyle (chylothorax). My co-surgeon, Jack H. Boyd, M.D., performed a partial pericardiectomy on Mr. Valadez. Both operative procedures occurred on February 17, 2022. Attached hereto as **Exhibit C** is a true and correct copy of the Operative Reports dated February 17, 2022. Dr. Boyd and I found "[d]iffuse tumor involvement of the pericardium with areas of invasion into the myocardium." [Exh. C at 119, 121.] The clinical

diagnosis included bilateral pleural effusions from chylothorax, pericardial constriction, and pericardial mesothelioma. [*Id*. at 118.]

10. I have reviewed the Progress Notes of Mr. Valadez's treating oncologist Dr. Mohana Roy dated March 18, 2022, a true and correct copy of which is attached hereto as **Exhibit D**. In her notes, Dr. Roy took Mr. Valadez's social history. [Exh. D at 189.] She noted that Mr. Valadez's mother "reports using large amounts of baby powder (Johnson and Johnson) in [Anthony's] childhood." [*Id*.] Dr. Roy also stated that there are "no other exposures to hair salon products, chemicals in labs," and "no clear asbestos exposure" from attending school "in an old building." [*Id*.] Further, ever since his diagnosis, Mr. Valadez has suffered from anxiety. [*Id.* at 191.]

11. I have reviewed Dr. Roy's Progress Notes dated May 6, 2022, a true and correct copy of which is attached hereto as **Exhibit E.** Dr. Roy stated that Mr. Valadez underwent two rounds of chemotherapy but was unable to do a third cycle because of his fatigue, cytopenia, and anemia. The day before this visit with Dr. Roy, Mr. Valadez had a CT scan of his chest which showed "increased diffuse nodular interlobular septal thickening, right greater than left lung, as well new and increasing pulmonary nodules," which is "concerning for progression of disease." There was "[e]xtensive thoracic lymphadenopathy and multiple pericardial masses nearing encasing the heart." Because his CT scan shows progression of disease, Mr. Valadez's chemotherapy treatments were put on hold and he will instead undergo immunotherapy.

12. Malignant mesothelioma is an aggressive cancer with a grave prognosis that is almost universally fatal. The risk of adverse effects, including death, the probability that severe complications of treatment will occur, and the likelihood of opportunistic infections or

unexpected rapid tumor progression, is very high. During my thoracic surgery practice, I have treated other patients with mesothelioma.

13. There is no cure for mesothelioma. The interval between diagnosis and death is often short (average 6 months). The average life expectancy is less for patients diagnosed with pericardial mesothelioma, like Mr. Valadez. Indeed, many of the cases of pericardial mesothelioma reported in the literature were not diagnosed until after death, because it is so aggressive. Patients who are diagnosed with mesothelioma may undergo treatment, such as chemotherapy, surgery, and/or radiation with the purpose of slowing the progression of the mesothelioma. These treatments do not cure mesothelioma and are considered palliative. Even if the patient is a proper candidate and elects to undergo treatment, the treatment may have only a modest impact on the patient's survival. Mr. Valadez has not tolerated chemotherapy well. His tolerance to chemotherapy will continue to decline as his mesothelioma rapidly advances. As his disease rapidly progresses, Mr. Valadez's discomfort, fatigue, disruption of normal body processes, and pain will continue and increase in severity, despite intervening pain medication and treatment. The most likely outcome is that Mr. Valadez ultimately will die of complications from mesothelioma.

14. Another source of pain and discomfort for Mr. Valadez is his Pleural-X catheters. They remain in place as treatment of his refractory chylothoraces, which are likely a consequence of lymphatic congestion from his tumor. The catheters require care and upkeep to keep Mr. Valadez's effusions from reaccumulating and contributing to symptoms such as shortness of breath.

15. The pericardial mesothelioma from which Mr. Valadez suffers can change clinical and symptomatic directions quite quickly. Several factors may influence the progression of

cancer, including the side effects from therapy, alterations of the normal physiology, and stress, which has both emotional and physical components. Mr. Valadez has anxiety and fear because of his terminal mesothelioma, which are known emotional stressors in terminal cancer patients. Many types of stress activate the body's endocrine (hormone) system, which in turn can alter the way the immune system functions. Fatigue is also a major psychological symptom. Fatigue is the most common and distressing symptom associated with cancer and cancer therapies. Physical and emotional stress both contribute to a cancer patient's fatigue and fatigue generally becomes progressively worse as a malignancy progresses. As his illness progresses, Mr. Valadez will become less able to attend trial and participate meaningfully in litigation. A prolonged case lasting over a period of many months can increase a patient's stress level and exacerbate fatigue, with its attendant negative consequences to the patient's cancer fighting ability.

16. I have reviewed numerous medical articles that report the relationship between pericardial mesothelioma and asbestos exposure. For example, the World Health Organization states that like "pleural mesothelioma, a large portion of mesotheliomas of the pericardium are induced by asbestos." [World Health Organization Classification of Tumors (2004) at p. 286, a true and correct copy of which is attached hereto as **Exhibit F**.]

17. Cases of mesothelioma have been observed in persons who have used cosmetic talc powder. [Emory, et al., *Malignant Mesothelioma Following Repeated Exposures to Cosmetic Talc: A Case Series of 75 Patients* (2020) Am. J. Ind. Med. 484, a true and correct copy of which is attached hereto as **Exhibit G**.] In Emory, et al., a patient whose only known exposure to asbestos was repeated use of cosmetic talc powder later developed pericardial mesothelioma. [*Id.* at 484-486.]

18. Based on (i) my examination and treatment of Mr. Valadez, (ii) my review of his medical records, (iii) my experience and training involving mesothelioma patients, (iv) the aggressive nature of Mr. Valadez's cancer, (v) the distinct progression of his mesothelioma, and (vi) my review of the scientific literature, including those identified above, it is my professional medical opinion that there is substantial medical doubt of Mr. Valadez's survival beyond six months from the date of this declaration. Further, based on Mr. Valadez's social history as documented above, the only dusty activity he has encountered in his life on a regular basis is his use of Johnson's Baby Powder. Based on the factual assumption regarding the asbestos content of Johnson's Baby Powder, it is my opinion, to a reasonable degree of scientific and medical certainty, that it is more likely than not that Mr. Valadez's exposure to asbestos stemming from Johnson's Baby Powder increased his risk of developing mesothelioma, and that asbestos was the cause of his pericardial mesothelioma.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief. I executed this Declaration on May 22, 2022 at Saratoga, California.

By: DocuSigned by: Leah Backhus EC7F78D98CE0422...
LEAH MONIQUE BACKHUS, M.D., MPH, FACS

Exhibit A

Leah Monique Backhus MD MPH FACS

lbackhus@stanford.edu

Stanford University
Department of Cardiothoracic Surgery
300 Pasteur Drive
Falk Research Building
Palo Alto, CA 94305-9407
650-721-6400 (Office)

VA Palo Alto Health Care System
Cardiothoracic Surgery
3801 Miranda Ave
Palo Alto, CA 94304
650-493-5000 Ext. 11-65682

Personal Data:

Maiden Name:	Leah Monique Fuller
Place of Birth:	New Jersey, USA
Current Address:	19223 Harleigh Drive Saratoga, CA 95070

Current Positions:

07/01/2015-present	Associate Professor Department of Cardiothoracic Surgery Stanford University
07/01/2015-present	Section Chief Thoracic Surgery VA Palo Alto Health Care System

Previous Positions:

2009-2015	Assistant Professor	Department of Surgery Division of Cardiothoracic Surgery University of Washington
	Chief	Thoracic Surgery VA Puget Sound Healthcare System
	Staff Surgeon	Northwest Hospital

Residency:

2007-2009	Chief Resident	Cardiothoracic Surgery, Thoracic Track University of California Los Angeles Los Angeles, CA
2000-2007	Resident	General Surgery University of Southern California Los Angeles, CA

Education:

2012-2014	MPH	Health Services

		School of Public Health University of Washington
1996-2000	MD	Keck School of Medicine University of Southern California
1991-1995	AB	Human Biology Stanford University

Research:

2016-present	**Faculty Member**, Stanford-Surgery Policy Improvement Research & Education Center
2015-present	**Co-Director**, Thoracic Surgery Clinical Research Program, Stanford University
2015-present	**Center Investigator**, VA Palo Alto Health Services Research & Development
2012-2015	**Scholar**, Institute of Translational Health Science, University of Washington
2011-2015	**Principal Investigator**, VA Puget Sound Healthcare System Lung Cancer Tissue and Blood Repository
2003-2005	**Research Fellow**, Department of Cardiothoracic Surgery, Keck School of Medicine, University of Southern California
1998	**Research Associate**, Department of Surgery, Keck School of Medicine, University of Southern California
1996	**Research Associate**, Department of Neurosurgery, Keck School of Medicine, University of Southern California
1992-1995	**Research Assistant**, Department of Molecular Pharmacology, Stanford University

Board Certification:
American Board of Surgery Certificate # 052964 1/28/2008, Recertified 12/31/2019, 09/22/2020
American Board of Thoracic Surgery Certificate # 7631 6/11/2010, Recertified 12/4/2020

Licensure:
California State Medical Board A77191 (Active)
Washington State Medical Board MD60097561 (Inactive)

Professional Memberships:
American Association for Thoracic Surgery
Society of Thoracic Surgeons
American College of Surgeons, Fellow
Society of University Surgeons
American Society of Clinical Oncology
International Association for the Study of Lung Cancer
International Thymic Malignancy Interest Group
Women in Thoracic Surgery
Society of Black Academic Surgeons
American Medical Association
Association of Women Surgeons
Henry N. Harkins Surgical Society

International Professional Committees:

European Society of Thoracic Surgeons
2020-present **Member**
2020-present **Core Member**, Women in General Thoracic Surgery Committee

International Association for the Study of Lung Cancer
2020-present **Member**, Women in Thoracic Oncology
2018-2023 **Member**, Membership Committee

European Lung Cancer Congress (European Society for Medical Oncology and International Association for the Study of Lung Cancer)
2021-2022 **Member**, Scientific Committee

National Professional Committees:

National Institutes of Health: National Cancer Institute
2021-present **Faculty Member**, Division of Cancer Control and Population Sciences Planning Committee for workshop Issues in Evidence for Post-Treatment Surveillance Strategies for lung Cancer

American Association for Thoracic Surgery
2022-2023 **Member**, AATS Women in Cardiothoracic Leadership Task Force
2021-2022 **Member**, Writing Group Thoracic: Early Lung Cancer
2021-2024 **Member**, Equity & Career Development Scholarship Committee, **AATS Foundation**
2020-2023 **Member**, Thoracic Surgery Scholarship Committee
2019-2023 **Member**, Membership Recruitment, Engagement and Diversity Committee

Society of Thoracic Surgeons
2019-present **Director-at-Large**, Board of Directors
2021-2024 **Member**, Standards and Ethics Committee
2019-2023 **Member**, Workforce on Diversity and Inclusion
2019-2023 **Ex-officio Member**, Council on Health Policy and Relationships Operating Board
2020-2022 **Faculty Member/Organizer**, STS Leadership Institute
2020-2022 **Member**, Virtual Meeting Task Force
2019-2022 **Member**, Workforce on Thoracic Surgery Resident Issues
2018-2024 **Member**, Workforce on Health Policy, Reform, and Advocacy
2017-2019 **Member**, Task Force on Diversity and Inclusion
2012-2017 **Member**, Membership Committee
2012-2017 **Member**, Media Relations Committee
2013-2015 **Co-Chair**, Workforce on Annual Meeting Surgical Symposia Taskforce

Thoracic Surgery Foundation
2021-present **Member**, Research Awards Committee

American College of Surgeons
2022 **Abstract Reviewer**, Annual Meeting Program Committee
2021 **Abstract Reviewer**, Annual Meeting Program Committee
2020 **Abstract Reviewer**, Annual Meeting Program Committee

Western Thoracic Surgical Association
2016-2019 **Member**, Annual Meeting Program Committee
2017-2018 **Chair**, Annual Meeting Program Committee
2014-2016 **Member**, Membership Committee
2014-2015 **Chair**, Local Arrangements Committee

Women in Thoracic Surgery
2019-2022 **Secretary/Treasurer**, Board of Directors
2014-2019 **Director-at-Large,** Board of Directors

Accreditation Council for Graduate Medical Education
2022-2022 **Board Member,** Taskforce on Diversity
2019-2022 **Chair**, Thoracic Surgery Review Committee
2018-2019 **Vice-Chair**, Thoracic Surgery Review Committee
2016-2018 **Member**, Thoracic Surgery Review Committee

Society of University Surgeons
2021-2024 **Member**, Membership Committee

National Lung Cancer Roundtable of the American Cancer Society
2018-present **Chair of the Lung Cancer in Women Task Group**
The NLCRT is a collaboration of public, private and voluntary organizations who play a key role in reducing the incidence of and mortality from lung cancer. The NLCRT will more rapidly advance lung cancer control through efforts to increase public and professional education, prevention and early detection, quality assurance, access to care, effective health policy, and optimal diagnosis and treatment for cancer patients. The Lung Cancer in Women Task Group will focus on acknowledging that lung cancer is a women's health imperative, and its disparate impact on women to devise public health awareness campaigns specific to women emphasizing the importance of early detection.

Surgical Outcomes Club
2019-present **Member**

Patient Centered Outcomes Research Institute:
2016-2019 **Member**, Health Delivery and Disparities Research Advisory Panel

American Society of Clinical Oncology.
2016-2019 **Member**, Annual Program Committee Thoracic Tract

<u>*Society of Black Academic Surgeons*</u>

2016-2020 **Member**, Annual Program Committee

<u>*Veterans Health Administration*</u>

2021-present **Clinical Champion**, National Oncology Program: National Esophageal Oncology Pathways Team
2020-2021 **Clinical Champion**, National Oncology Program: National Lung Oncology Pathways Team

Local Committee Membership/Service to the University:

2021-present **Wellness Director**, Stanford Department of Cardiothoracic Surgery
2021 **Panelist**; Stanford Department of Radiology Justice, Diversity, Equity, and Inclusion Mentorship
2021-2023 **Medical Executive Committee Service Representative**; Stanford Healthcare
2021-present **Selection Committee Member** McCormick and Gabilan Faculty Awards; Stanford School of Medicine
2021-present **Faculty Advisory Board**; Stanford Center for Continuing Medical Education (SCCME) Faculty Leadership Development Certificate Program
2020-present **Steering Committee Member**; Stanford Black Faculty Affinity Meeting (BFAM)
2020-2023 **Member**; Stanford Healthcare Committee on Professionalism
2020 **Faculty Speaker;** *Medical Specialties and Subspecialties Workshop*; Stanford University Minority Medical Alliance (SUMMA) Annual Meeting
2018-present **Member**; Stanford Department of Cardiothoracic Surgery, Departmental Appointments and Promotions Committee
2016-2020 **Member**; Stanford Healthcare Health Information Management Committee
2016-2018 **Member**; Stanford Women and Sex Differences in Medicine (WSDM)
2013-2015 UW Department of Surgery Diversity Council
2012-2015 Center for Equity Diversity and Inclusion Executive Steering Committee
2013-2015 Executive Board Member; UW Committee on Minority Faculty Affairs
2009-2015 UW School of Medicine Committee on Women
2009-2015 VA Puget Sound Healthcare System Operating Room Committee
2009-2015 VA Puget Sound Healthcare System Physician Utilization Management Committee
2009-2015 UW School of Medicine African American Mentoring Network
2009-2013 Chair; UW Committee on Minority Faculty Affairs
2009-2011 UW School of Medicine Medical School Admissions Committee
2009-2011 Sub-committee Chair; UW School of Medicine Dean's Diversity Strategic Planning Committee

Awards/Honors:

2019 Thoracic Surgery Foundation Levi Watkins Innovation and Leadership Development Scholarship
2019 Thoracic Surgery Residents Association (TSRA) McGoon Teaching Award
2018 Alpha Omega Alpha Medical Honor Society Faculty Inductee
2017 Stanford Dean’s Leadership Development Program Awardee

2012 Superior Performance Award, for exemplary performance and dedication to the VA Puget Sound Health Care System
2011 AAMC Early Career Women Faculty Career Development, Recipient
2010 Society of Black Academic Surgeons Leadership Council Award
2010 AAMC Minority Faculty Development Program, Recipient
2009 AATS Resident Traveling Fellowship Award Recipient
2008 Peter C. Pairolero Resident Scholarship Award Recipient, General Thoracic Surgery Club
2005 Society of Black Academic Surgeons Leadership Council Award
2001 Annual Resident Teaching Award, Department of Surgery, University of Southern California
2000 Sagar Gupta, MD Memorial Scholarship Award, University of Southern California
1996 Gerber Scholarship, University of Southern California

Teaching:

2021 *Stanford Cardiothoracic Surgical Skills Summer Internship* Invited Speaker Stanford School of Medicine, Stanford, CA
2018-2021 Ethnicity in Medicine: *Vulnerable populations underappreciated in the fight against lung cancer*; Stanford University; Department of Human Biology, Stanford, CA
2018-2021 *Service through Surgery Conversation*; Stanford School of Medicine, Stanford, CA
2018 Stanford Summer Community College Premedical Program: *Health Disparities in Lung Cancer*; Center of Excellence in Diversity in Medical Education Stanford School of Medicine, Stanford, CA
2016 Stanford Emergency Department Thoracic Surgery Clinical Practicum
2015-present Associate Program Director; Stanford University CT Surgery Residency Program, Thoracic Track
2014-2015 Site Director: UW CT Surgery Residency Program
2013-2015 Contributor; TSDA On-line Clinical Case Curricula
2013-2015 Mentor; UW School of Medicine; Underserved Pathway
2009-2015 Faculty Advisor; UW School of Medicine Student Surgical Interest Group;
2010 Faculty Advisor; UW School of Medicine; Introduction to Clinical Medicine: *Images of Physicians Series*
2003-2005 Clinical Instructor; USC Keck School of Medicine; Introduction to Clinical Medicine

Invited Lectures:

<u>*National/International*</u>

2022 *Role of Surgery in Oligometastatic Disease*; European Lung Cancer Congress, Prague, CZ
2022 *Moving Towards a patient-centered approach to Surveillance After treatment for Lung Cancer;* **Grand Rounds Lecture**; University of Colorado Department of Surgery, Denver, CO

2022 *Moving Towards a patient-centered approach to Surveillance After treatment for Lung Cancer;* **Grand Rounds Lecture**; University of Washington Department of Surgery, Seattle, WA
2021 *Healthcare Disparities and Cardiothoracic Diversity in Europe;* **ESTS 2021 Annual Meeting**: **Co-Moderator**; ESTS-EACTS Joint Session, Virtual Meeting
2021 *Unconscious Bias and Communication in the Operating Room*; **AATS 2021 Annual Meeting**: Patient Safety Forum
2020 *Challenges in Post-Operative Surveillance for Early Stage Lung Cancer;* **AATS Foundation Gardner Lectureship**; UC Davis Department of Surgery, Sacramento, CA
2019 *Challenges in Post-Operative Surveillance for Early Stage Lung Cancer;* **UCLA Department of Surgery Grand Rounds**, Los Angeles, CA
2019 *Management of Subsolid Nodules (North Am perspective);* **European Association for Cardiothoracic Surgery (EACTS) Annual Meeting**; Lisbon, Portugal
2019 *Women in Thoracic Surgery: US Perspective*; In Co-Operation with Women In Thoracic Surgery; **Session Co-Chair; European Society of Thoracic Surgeons (ESTS) Annual Meeting**; Dublin, Ireland
2019 *Lung Cancer and Women, Gender Differences in Clinical Outcomes;* **National Lung Cancer Roundtable 2019** Women and Lung Cancer Task Group Summit; Atlanta, GA
2017 *Surveillance for Lung Cancer*; **International Association for the Study of Lung Cancer (IASLC) 2017 Multidisciplinary Symposium in Thoracic Oncology**; Chicago, IL
2017 *Management of Pleural Disease*; **American College of Surgeons Clinical Congress, Session Co-Moderator**; San Diego, CA
2017 *PCORI Grant Funding Process;* **AATS Grant Writing Seminar**; Bethesda, MD
2016 *Pleural Disease;* **Association of Physician Assistants in Cardiovascular Surgery**; Las Vegas, NV
2015 *Surveillance and Survivorship Care in Lung Cancer;* **Thoracic Oncology Symposium sponsored by NCCN; Seattle Cancer Care Alliance**; UW Medicine; Seattle, WA
2013 *Surveillance and Survivorship Care in Lung Cancer;* **Thoracic Oncology Symposium sponsored by NCCN, Seattle Cancer Care Alliance**; UW Medicine; Seattle, WA
2012 *New Lung Cancer Screening Guidelines*; **Annual Conference on Advanced Practice in Primary & Acute Care**; Seattle, WA
2011 *Pulmonary Metastatic Disease;* **Thoracic Surgery Directors Association National Curriculum Lecture**: (http://www.tsda.org/sections/integrated_curriculum/TSDA Weekly Curricula)
2011 *Pulmonary Metastasectomy;* **Thoracic Surgery Directors Association National Curriculum Lecture**: (http://www.tsda.org/sections/integrated_curriculum/TSDA Weekly Curricula)

Regional/Local

2021 WTSA Annual Meeting Controversies Debate: *Managing the Cardiothoracic Workforce During a Public Crisis: Repercussions for the Trainee*, Phoenix, AZ
2021 USC Advancing Knowledge in Lung Cancer Care; *Challenges to Surveillance Following Treatment for Lung Cancer*; Los Angeles, CA

2021 Best of World Conference on Lung Cancer; International Association for the Study of Lung Cancer (IASLC): *Controversies in Locally Advanced NSCLC*; San Francisco, CA
2021 Stanford School of Medicine Office of Diversity in Medical Education (ODME) 4th Annual Diversity and Inclusion Forum; Plenary Speaker; *Academic Medicine Career Roles and Responsibility*; Stanford, CA
2021 University of California, San Diego Department of Surgery Grand Rounds: *Challenges in Post-Operative Surveillance for Early Stage Lung Cancer;* San Diego, CA
2021 Stanford University Minority Medical Alliance (SUMMA) Annual Conference: Medical Specialty Workshop
2020 University of California, Davis Visiting Faculty Scholar Departments of Surgery: *Current State of Surveillance and Survivorship Care in Lung Cancer*; Sacramento, CA
2019 WTSA Annual Meeting, Resident Symposium: *Tips for Professional and Personal Satisfaction;* Lake Tahoe, CA
2019 Moderator, WTSA Annual Meeting, Concurrent Forum: Thoracic Surgery: *Moderator*; Lake Tahoe, CA
2019 Moderator, Northern California Chapter of the American College of Surgeons (NCCACS) 2019 Annual Educational Meeting: *Diversity and Inclusion in Surgery –The Return on Investment*; Berkeley, CA.
2019 Northern California Chapter of the American College of Surgeons (NCCACS) 2019 Annual Educational Meeting: *Gender Inclusion and the Culture of Safety in Healthcare*; Berkeley, CA.
2019 UCLA Department of Surgery Grand Rounds Lecture Series; *Imaging Surveillance After Lung Cancer Treatment: Moving Towards Precision Medicine*; Los Angeles, CA
2018 Moderator, WTSA Annual Meeting, Resident Symposium; Santa Barbara, CA
2017 WTSA Annual Meeting, Resident Symposium: *Interview Preparation*; Colorado Springs, CO
2017 Cancer Education Seminar Series, Stanford University: *Surveillance and Survivorship in NSCLC*
2016 Early Riser Session, STS Annual Meeting: *Patient-Centered Care: Surveillance*
2016 Cancer Education Seminar Series, Stanford University: *Surveillance and Survivorship in NSCLC*
2015 VISN 20 Pulmonary SCAN Clinical Conference, VA Puget Sound: *Transition in Care Following Lung Cancer Treatment*
2015 Washington Thoracic Society 25th Annual Chest Conference and Winter Lung Day. *Lung Cancer Debate: Stage III Disease is a Surgical Disease*
2014 Oregon Health & Science University (OHSU) Visiting Faculty Scholar. The Departments of Radiation Medicine & Surgery: *Current State of Surveillance and Survivorship Care in Lung Cancer*
2014 VISN 20 Pulmonary SCAN Clinical Conference, VA Puget Sound: *Pre-Operative Evaluation Of The Patient Undergoing Lung Surgery*
2013 VISN 20 Pulmonary SCAN Clinical Conference, VA Puget Sound: *Surgical Management of COPD: Lung Volume Reduction Surgery*
2013 Pulmonary Educational Conference, VA Puget Sound: *Radiographic Evaluation of the patient with lung cancer: Surgical implications of imaging*
2012 Radiology Resident Lecture: *Radiographic Evaluation of the patient with lung cancer: Surgical implications of imaging*

2011 University of Washington Leadership Retreat: *"Dean's Strategic Planning Committee on Minority Affairs: Subcommittee Report on Best Practices in Minority Faculty Development"*
2010 Society of Thoracic Surgeons: Resident Luncheon Invited Speaker
2010 PGY1 class (ISIS): *Thoracostomy Lecture and Practical*

Research Funding:

Current:

11/1/21-12/1/24 **Co-Investigator**
Single-cell Transcriptomic and Epigenetic Atlas of Multi-Ancestry Hearts; (PI: Joseph Wu) Chan-Zuckerberg Initiative

10/1/21-9/30/22 **Principal Investigator**
Multimodal Intervention Strategies to Improve Lung Cancer Screening for Women Undergoing Breast Screening ; (PI: **Backhus**) Stanford Comprehensive Cancer Center Clinical Innovation Award

9/1/18-8/31/22 **Co-Principal Investigator**
"*A Mechanistic Clinical Trial of JAK Inhibition to Prevent Ventilator-induced Diaphragm Dysfunction*"; (PI: Shrager/**Backhus**) NIH: Skeletal Muscle Exercise Physiology Study Section (1 R01 HL148185-01)

12/1/18-12/31/23 **Principal Investigator**
"*iSALT: Imaging Surveillance After Lung Cancer Treatment";* (PI: **Backhus**) VA HSR&D IIR Merit Award (HX002456-01A2)

Completed:

2016-2017 **Co-Investigator;**" Use of Natural Language Processing and Machine Learning *to Identify Newly Diagnosed and Recurrent Cases of Cancer in VHA EHR Records"* (PI: Zeliadt); VA HSR&D IIR
2015-2016 **Principal Investigator**; *"Pre-Operative Optimization Program to Improve Surgical Outcomes for Veterans"*; VA HSR&D Locally-Initiated Projects Award, Palo alto
2013-2016 **Co-Investigator**; *"A Novel Approach to measuring costs and efficiency: Lung nodules as a case study"* (PI: Zeliadt); VA HSR&D (IIR 12-065-3)
2012-2015 **KL2 Award Scholar**; NIH/NCATS National Center for Research Resources, 2 KL2 TR000423-07 KL2 ITHS Multidisciplinary Clinical Research Training Program
2012-2013 **Co-Investigator**; "*Barriers to Accessing Care for Outpatients Newly Diagnosed with Lung Cancer*" (PI: Reinke); VA Office of Nursing Services (ONS)
2012-2013 **Co-Investigator**; "*Palliative Care Interventions for Outpatient Veterans Newly Diagnosed with Lung Cancer*" (PI: Reinke); Nursing Research Initiative Grant; VA Office of Nursing Services (ONS)
2004-2005 Los Angeles Heart and Lung Foundation
2003-2004 Los Angeles Heart and Lung Foundation

Peer-Review: Grant Reviewer:

2021-present	Charter Member Reviewer, NIH Imaging Guided Interventions and Surgery (IGIS) study section
2020	Ad hoc Reviewer, NIH Imaging Guided Interventions and Surgery (IGIS) Study section
2018-present	**ad hoc Reviewer**, National Institutes of Health: Dissemination and Implementation Research in Health (DIRH) Study Section

Peer-Review: Journal Editing:

2022-present	Deputy Editor, *JAMA Surgery*
2021	Guest Co-Editor. *JTD*. *Focused Issue*: Women in Thoracic Surgery. Vol 13, No 1

Peer-Review: Journal Reviewer:

2019-present	Reviewer, *Advances in Health Care Management*
2016-present	Reviewer, *Journal of the National Comprehensive Cancer Network*
2014-present	Reviewer, *Journal of Thoracic and Cardiovascular Surgery*
2014-present	Reviewer, *Annals of Thoracic Surgery*
2012-present	Reviewer, *Diseases of the Esophagus*
2012-present	Reviewer*, Journal of Heart and Lung Transplantation*
2011-present	Reviewer, *Annals of Surgical Oncology*
2017-2019	Reviewer, Research Reports, *Patient-Centered Outcomes Research Institute*

Other/Community Service:

2020	Gender Barriers in Medicine Panel – Stanford School of Medicine; Sexual Harassment/Assault Response Education Title IX Office
2020	Speaker: Stanford's Health Career Collaborative - East Palo Alto Academy
2020	Speaker: Future Doctors and Nurses Club at LACES high school – Los Angeles, CA
2020	The Peninsula College Fund, Speaker/Mentor: Career Exploration Fair
2013-2015	VISN 20 Pulmonary SCAN (Specialty Care Access Networks – Extension for Community Healthcare Outcomes) Program, Role: Clinician Specialist
2011-2014	American College of Surgeons, Commission on Cancer Physician Liaison, VA Puget Sound Healthcare System
2011-2012	VA Puget Sound and VA Medical Center Spokane Lung Cancer Collaborative Project-Core Team Leader
2009-2015	Donate Life, Community Volunteer Lecturer

Mentoring:

2021-preent	Ghazal Aghagoli	Medical Student	Brown University
	Scanlan/Women in Thoracic Surgery Traveling Mentorship Award		
2021-present	McKenna Schimmel	Medical Student	University of Vermont
	STS Mentorship Program (Medical Student)		
2021-present	Kelli Salter	Attending	Piedmont Atlanta Hospital
	STS Mentorship Program (Surgeon)		

2020-present	Irmina Elliott	Resident	Stanford, CT Surgery
2020-2021	Oseitohanmen Okhiulu	Undergraduate Student	Stanford University
	Vice Provost for Undergraduate Education Undergraduate Research Major Grant; Research Advisor		
2020-present	Catheryn Byrd	Research Fellow	Stanford, CT Surgery
	Thoracic Surgery Clinical Research Program		
2020-2020	Courtney Obasohan	Undergraduate Student	UCLA
	Stanford Cardiovascular Institute's Undergraduate Summer Research Program NIH R25 grant (NHLBI - Short-Term Research Education Program to Increase Diversity in Health-Related Research)		
2019-present	Kiah Williams	Resident	Stanford, Cardiothoracic Surgery
2019-2020	Karen Gutierrez	Medical Student	Stanford School of Medicine
	Leadership in Health Disparities Summer Program (LDHP) LHDP is a seven-week program offered to matriculating medical students during the summer quarter preceding the first year of medical school. It is directed at initiating a successful medical and leadership career focused on increasing student's knowledge of health disparities and the roles of physician leaders.		
2018-present	Ioana Baiu	Resident	Stanford, General Surgery
2018-present	Ashley Titan	Resident	Stanford, General Surgery
2015-2019	Elizabeth Colwell	Resident	Stanford, Cardiothoracic Surgery
2017-2018	Ashni Nadgauda	Medical Student	Case Western Reserve
2016-2018	Douglas Liou	Resident	Stanford, Cardiothoracic Surgery
2014-2015	Mentor, *T32 UW CHASE Surgical Outcomes Post-Doctoral Training Program*		
	Agency: NIH/NIDDK		Grant #: DK070555
	Project Period:		07/01/2010-06/30/2015
2013-2015	Neli Mottey	Medical Student	UW, Underserved Pathway
2012-2015	Edo Bedzra	Resident	UW Cardiothoracic Surgery
2013-2015	Estelle Williams	Resident	UW General Surgery
2010-2015	Lara Oyetunji	Resident	UW General Surgery
2012-2014	Nathan Mollberg	Resident	UW Cardiothoracic Surgery
2012-2013	Jonathan Sargent	Medical Student	UW Medical Student Research Training Program
2010-2012	Awori Hayanga	Faculty	Cardiothoracic Surgery, University of Pennsylvania

Bibliography:

Peer Reviewed: Original Research

In Press:

1. Byrd C, Ajawara U, Laundry R, Radin J, Bhandari P, Leung A, Han S, Asch A, Zeliadt S, Harris A, **Backhus L**. Performance of a semi-automated method to optimize chart abstraction for characterization of surveillance imaging among patients treated for non-small cell lung cancer. (in press)

Published:

1. Keshinro A, Butler P, Fayanju O, Khabele D, Newman E, Greene W, Ude Welcome A, Joseph KA, Stallion A, **Backhus L**, Frangos S, DiMaggio C, Berman R, Hasson R, Rodriguez LM, Stain S, Bukur M, Klein MJ, Henry-Tillman R, Barry L, Oseni T, Martin C, Johnson-Mann C, Smith R, Karpeh M, White C, Turner P, Pugh C, Hayes-Jordan A, Berry C Examination of Intersectionality and the Pipeline for Black Academic Surgeons. *JAMA Surg*. 2022 Feb 9. doi: 10.1001/jamasurg.2021.7430. Online ahead of print. PMID: 35138327

2. Pompili C, Opitz I, **Backhus L**, Leschber G, Verones G, Lauk O, Novoa N, Daddi N, Deglurkar I, Cleuziou J, Emrich A, D'Auria F, Kluin J. ESTS and EACTS Gender Bias Survey. *Eur J Cardiothorac Surg*. 2022 Jan 29:ezac034. doi: 10.1093/ejcts/ezac034. Online ahead of print. PMID: 35092281

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10. Patel DC, Wang H, Bajaj SS, Williams KM, Pickering JM, Heiler JC, Manjunatha K, O'Donnell CT, Sanchez M, Boyd JH, **Backhus LM**. The Academic Impact of Advanced Clinical Fellowship Training among General Thoracic Surgeons. *J Surg Educ*. 2021 Oct 19:S1931-7204(21)00249-X. doi: 10.1016/j.jsurg.2021.09.003. PMID: 34674980

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17. Yang CJ, Hurd J, Lui N, **Backhus L**, Liou D, Shrager J, D'Amico T, Berry M. A National Analysis of Open vs Minimally Invasive Thymectomy for Stage I-III Thymoma. *J Thorac Cardiovasc Surg.* 2020 Aug;160(2):555-567.e15. doi: 10.1016/j.jtcvs.2019.11.114. Epub 2019 Dec 14. PMID: 32245668 *Presented at the American Association for Thoracic Surgery Annual Meeting 2019*

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19. Bryan D, Ferguson M, and members of the **Delphi Lobectomy Cooperative**. A Consensus for Thoracoscopic Left Upper Lobectomy-Essential Components and Targets for Simulation. *Ann Thorac Surg. 2020 Oct 27:S0003-4975(20)31739-2. doi:10.1016/j.athoracsur. 2020.06.152.*

20. Patel DC, Berry MF, Bhandari P, **Backhus LM**, Raees S, Trope W, Nash A, Lui NS, Liou DZ, Shrager JB. Paradoxical Motion on Sniff Test Predicts Greater Improvement Following Diaphragm Plication. *Ann Thorac Surg*. 2020 Oct 5;. doi: 10.1016/j.athoracsur.2020.07.049. [Epub ahead of print] PubMed PMID: 33031777

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Peer Reviewed: Other Publications

In Press

1. Entwistle JW, Drake DH, Fenton KN, Smith MA, Sade RM, for the **Cardiothoracic Ethics Forum.** Normothermic Regional Perfusion: Ethical Issues in Thoracic Organ Donation. *Annals* 2022

2. **Backhus LM**, Chang CF, Sakoda LC, Chambers SR, Henderson LM, Henschke C, Hollenbeck G, Jacobson FL, Martin LW, Proctor ED, Schiller JH, Siegfried JM, Wisnivesky JP, Wolf AS, Jemal A, Kelly K, Sandler KL, Watkins PN, Smith RA, Rivera MP. NLCRT Lung Cancer in Women Strategic Plan Manuscript Submission. *Cancer* 2022

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1. Byrd CT, Williams KM, **Backhus LM**. A brief overview of thoracic surgery in the United States. *J Thorac Dis.* 2022 Jan;14(1):218-226. doi: 10.21037/jtd-21-1504. Review. PMID: 35242386

2. Baiu I, Titan AL, Martin LW, Wolf A, **Backhus L**. The role of gender in non-small cell lung cancer: a narrative review. J Thorac Dis. 2021 Jun;13(6):3816-3826. doi: 10.21037/jtd-20-3128. PMID: 34277072

3. Elliott I, Gonzalez C, **Backhus L**, Lui N Social Disparities in Lung Cancer. *Thorac Surg Clin*. 2022 Feb;32(1):33-42. doi: 10.1016/j.thorsurg.2021.09.009.PMID: 34801193

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6. Pompili C, Brulls A, Elswick E, Masschelein K, **Backhus L.** Women in thoracic surgery: lesson learned from medical industry partners. *J Thorac Dis*. 2021 Jan;13(1):485-491. doi: 10.21037/jtd-2020-wts-02.PMID: 33569236

7. Preventza O, **Backhus L**. US women in thoracic surgery: reflections on the past and opportunities for the future. *J Thorac Dis*. 2021 Jan;13(1):473-479. doi: 10.21037/jtd.2020.04.13.PMID: 33569234

8. Pompili C, **Backhus L**. Time for change: women leading in cardiothoracic surgery, a global perspective. *J Thorac Dis*. 2021 Jan;13(1):430-431. doi: 10.21037/jtd-2020-wts-01.

9. Antonoff MB, Mitzman B, **Backhus L**, Bradbury ST, Chatterjee S, Cooke DT, Crestanello J, Goldstone AB, Kim KM, Nguyen TC, Romano JC, Vaporciyan AA, Varghese Jr. TK. Society of Thoracic Surgeons (STS) Virtual Conference Taskforce: Recommendations for Hosting a Virtual Surgical Meeting. *Ann Thorac Surg. 2021 Jan;111(1):16-23. doi: 10.1016/j.athoracsur.2020.10.008. Epub 2020 Nov 1. PMID: 33137298*

10. Antonoff M, **Backhus L**, Boffa DJ, Broderick SR, Brown LM, Carrott P, Clark JM, Cooke D, David E, Facktor M, Farjah F, Grogan E, Isbell J, Jones DR, Kidane B, Kim AW, Keshavjee S, Krantz S, Lui N, Martin L, Meguid RA, Meyerson SL, Mullett T, Nelson H, Odell DD, Phillips JD, Puri V, Rusch V, Shulman L, Varghese TK, Wakeam E, Wood DE.COVID-19 guidance for triage of operations for thoracic malignancies: A consensus statement from Thoracic Surgery Outcomes Research Network. *J Thorac Cardiovasc Surg*. 2020 Aug;160(2):601-605. doi: 10.1016/j.jtcvs.2020.03.061. Epub 2020 Apr 9. PubMed PMID: 32689703; PubMed Central PMCID: PMC7146695.

11. Guenthart BA, **Backhus LM**, Lui NS. Commentary: Lung Cancer Outcomes Reporting Within the VA System: Room for Improvement. *Semin Thorac Cardiovasc Surg*. 2020 Jun 20;. doi: 10.1053/j.semtcvs.2020.06.008. [Epub ahead of print] PubMed PMID: 32569647.

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13. **Backhus LM**, Kpodonu J, Romano JC, Pelletier G, Preventza O, Cooke DT. An Exploration of Myths, Barriers and Strategies for Improving Diversity Among STS Members. *Ann Thorac Surg*. 2019 Oct 5. pii: S0003-4975(19)31552-8. doi: 10.1016/j.athoracsur.2019.09.007. [Epub ahead of print]PMID:31593654

14. Erhunmwunsee L, **Backhus LM**, Godoy L, Edwards MA, Cooke DT. Report from the Workforce on Diversity and Inclusion-The Society of Thoracic Surgeons Members' Bias Experiences. *Ann Thorac Surg*. 2019 Nov;108(5):1287-1291. doi: 10.1016/j.athoracsur.2019.08.015. Epub 2019 Sep 11. PMID:31520637

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3. Patel DC, He H, Berry MF, Yang CJ, Trope W, Lui N, Liou DZ, **Backhus LM**, Shrager JB. Cancer diagnoses and survival rise as 65-year-olds become Medicare-eligible. *Presented at ASCO Annual Meeting 2020*

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7. Bading JR, Bremner RM, Sievers EM, Chen X, Bart RD, Park R, **Backhus LM**. Functional and marker MicroPET imaging in a murine model of orthotopic lung cancer. *Chest Meeting Abstracts* 2004 126: 748S-b-749S-b.

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Posters/Oral Presentations:

1. Disparity in Risk of Second Primary Lung Cancer Among Lung Cancer Patients in the United States" *Poster presentation at AACR-Disparity 2021*.

2. Titan AL, Okhilu J, Nesbit S, Baiu I, Lui N, Berry M, Shrager J, **Backhus L**. Screening mammography as a missed opportunity for lung cancer screening among high-risk women. *Pacific Coast Surgical Association Annual Meeting 2022*

3. Olive JK, Robinson JA, Brescia AA, Han JJ, Haney JC, Forbess JM, Varghese Jr TK, **Backhus LM**, Cooke DT, Preventza OA. Demographics of Integrated Thoracic Surgery Applicants and Residents: Is There a Leaky Pipeline? *Presented at the Southern Thoracic Surgical Association Annual Meeting 2021*

4. Okhiulu JO, Titan AL, Nesbit S, Lui NS, Liou D, Berry M, Shrager JB, **Backhus LM**. Quantifying screening mammography as a potential missed opportunity to improve lung cancer screening among high risk women. *Presented at the Society of Thoracic Surgeons Annual Meeting 2021.*

5. Lui N, Trope W, Guo HH, Gifford K, Bhandari P, Benson J, Liou D, **Backhus L**, Berry M, Shrager J. 3D Printed Model of the Mediastinum for Cardiothoracic Surgery Resident Education. *Presented at the American College of Surgeons Clinical Congress 2020*

6. Su C, Wu J, Neal J, Popat R, **Backhus L**, Leung A, Nagpal S, Wakelee HA, Han S. Impact of Low-Dose CT Screening for Primary Lung Cancer on Subsequent Risk of Brain Metastasis: Secondary Analysis of NLST. *Presented at World Conference on Lung Cancer 2020*

7. Patel DC, Bhandari P,Shrager JB, Berry MF, **Backhus LM**, Lui NS, Liou DZ. Concurrent Lung Resection during Esophagectomy does not Increase Perioperative Morbidity or Mortality. *Presented at the American College of Surgeons Clinical Congress 2020*

8. Benson J, Bhandari P, Lui N, Berry M, Liou D, Shrager J, Ayers K, **Backhus L**. Incorporation of a Multimedia Education Platform Improves Peri-operative Teaching for Lung Cancer Patients. *Presented at the Western Thoracic Surgical Association Annual Meeting 2020*

9. Baiu I, Bhandara P, Titan A, Wang Y, Liou DZ, Lui NS, Shrager JB, Berry MF, **Backhus LM**. Impact of Timing of Surgery on Outcomes as Part of Multimodality Treatment for Malignant Pleural Mesothelioma. *Presented at the American Association of Thoracic Surgery Annual Meeting 2020*

10. Williams K, Wang H, Bajaj S, O'Donnell C, Sanchez M, Hironaka C, **Backhus L**, Boyd J. Gender Disparities in Academic Cardiothoracic Surgery. *Presented at the American Heart Association Annual Meeting 2020*

11. Yang CJ, Wang Y, He H, Liou D, Lui N, Berry M, Shrager J, **Backhus L**. A National Evaluation of Short-term and Intermediate-term Readmission after Esophagectomy. *Presented at the American College of Surgeons Clinical Congress 2019*

12. Benson J, Ayers K, Lee A, Dejesus-Cortez A, Lui N, Berry M, Shrager J, **Backhus L**. Development of an Innovative Multimedia Educational Platform to Improve Patient Education in The Peri-Operative Setting. Presented at the *Society of Black Academic Surgeons Annual Meeting 2019*

13. Titan A, He H, Lui N, Liou D, Berry M, Shrager J, **Backhus L**. An Examination of Hormone Replacement Therapy and Reproductive History on Lung Cancer Incidence and Mortality in the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial. *Presented at the American Association for Thoracic Surgery Annual Meeting 2019*

14. Odell DD, Cooke DT, Meguid R, **Backhus L**, Krantz S, Varghese T; Bilimoria K. Development of Consensus Measures of Lung Cancer Quality through a Modified Delphi Process. *Presented at the Society of Thoracic Surgeons Annual Meeting 2019*

15. Yang CF, Brown AB, Liou DZ, Lui NS, **Backhus LM**, D'Amico TA, Shrager JB, Berry MF The Oldest Old: A National Analysis of Outcomes for Patients 90 Years or Older with Non-small-cell Lung Cancer. *Presented at the Society of Thoracic Surgeons Annual Meeting 2019*

16. Yang CJ, Deng J, Wang X, Lui N, **Backhus L**, Shrager J, D'Amico T, Berry M. A National Analysis on the Impact of VATS Procedural Volume on Thoracoscopic Lobectomy Outcomes. *Presented at the Society of Thoracic Surgeons Annual Meeting 2019*

17. Yang CJ, Shah S, Demos D, **Backhus L**, Lui N, D'Amico T, Berry M. Long-term Survival after Surgery versus Chemoradiation for Proximal Esophageal Squamous Cell Carcinoma. *Presented at American Association for Thoracic Surgery 2018.*

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19. Pompili C, Edwards M, Bhandari P, Naunheim K, Novoa N, Brunelli A, **Backhus L**. Post Resection Lung Cancer Surveillance: Comparisons of practice between STS, ESTS and JACS Members. *Presented at World Conference on Lung Cancer 2018.*

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25. Liou D, **Backhus L**, Shrager J, Berry M. Induction Therapy for Locally Advanced Distal Esophageal Adenocarcinoma: Is Radiation Always Necessary? *Presented at AATS Annual Meeting 2017.*

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27. **Backhus L**, Ferrara L, Reinke L, Au D, Zeliadt S, Edwards T. The importance of patient recall within cancer survivorship care for improved post-treatment surveillance in lung cancer survivors. *Poster presented at the International Association for the Study of Lung Cancer: World Conference on Lung Cancer 2016*

28. Gao RW, Berry MF, Khuong A, Neal JW, **Backhus LM**, Shrager JB. Risk Factors for Progression of Ground Glass Opacities in Patients with Resected Pulmonary Adenocarcinoma. *Poster presented at AATS Annual Meeting 2016*

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30. Shaffer R, Tsai C, **Backhus LM**, Curtin C, Hernandez-Boussard T. Identification of targets to improve return to Emergency Room and Hospital Readmission among patients undergoing thoracotomy procedures. *Poster presented at American Thoracic Society 2016*

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35. Zeliadt SB, Makarov DV, Au DH, Zhou XA, **Backhus LM**. Frequency of unnecessary imaging prior to Choosing Wisely among Veterans diagnosed with low-risk cancer. *Presented at Academy Health 2014*

36. Mollberg N, Farhood F, Howell E, Ortiz J, **Backhus L**, and Mulligan M. The Impact of Primary Caregivers on Long-term Outcomes after Lung Transplantation. *Presented at ISHLT 2014*

37. Farjah F, **Backhus LM**, Varghese TK, Manning JP, Cheng AM, Mulligan MS, Wood DE. External Validation of a Prediction Model for Pathologic N2 in Radiographically Early-Stage Lung Cancer Patients. *Presented at AATS 2014 Annual Meeting*

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39. Farjah F, Varghese T, Mulligan M, Wood D, Cheng A, Alfonso-Cristancho R, Flum D, **Backhus L**. 90-Day Costs Associated with VATS and Open Lobectomy. *Presented at STS 2014*

40. **Backhus LM**, Zeliadt SB, Reinke LF, Rue T, Au DH. Challenges faced by lung cancer survivors in contrast to other cancer survivors in the U.S. *Poster at American College of Surgeons Clinical Congress 2013*

41. **Backhus L**, Acosta D. UW Medicine Dean's Standing Committee on Minority Faculty Affairs: An Alternative Model Worth Considering. *Presented at AAMC Group on Diversity and Inclusion Professional Development Conference 2013.*

42. **Backhus L**, Sargent J, Cheng A, Zeliadt S, Wood D, Mulligan M. Outcomes in Lung Transplantation Following Prior Lung Volume Reduction Surgery in a Contemporary Cohort. *Presented at the Western Thoracic Surgical Association Annual Meeting 2013.*

43. Reinke LF, Vig EK, **Backhus LM** , Wu D, Uman J, Wynar B, Au DH. Palliative Care Needs for Veterans Newly Diagnosed with Lung Cancer. *Oral Presentation at the MASCC – International Cancer Care Symposium 2012*

44. Slatore CG, Zeliadt SB, **Backhus LM**, Kessler LG, Hu E, Au. A Comparative Effectiveness Study of Pre-Operative PET Imaging and the Reduction of Unnecessary Lung Cancer Surgery. *Oral Presentation at HSR&D/QUERI National Conference 2012.*

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Temporal Trends in PET/CT Imaging and Impact on Surgical Resection Among Veterans with Non-Small Cell Lung Cancer. *Oral Presentation at the 48th Annual Meeting of the Society of Thoracic Surgeons 2012.*

46. **Backhus LM,** Pergam SA, Dick A, Maynard, Forsberg CW, Spigner C, Rees C, Smith N, Young B. Long-term Evaluation of Solid Organ Transplant Rejection Risk among Veterans from 1995-2007. *Poster Presented at SBAS Annual Meeting 2011*

47. Spigner C, Rees Lyles C, Galvin G, Sabin J, Dick A, **Backhus L**, Davis C, Young B. Providers' View of Patient Education: A Qualitative Study: Increasing Kidney Disease Awareness Network (IKAN) Transplantation Project. *Poster Presented at the World Congress of Nephrology 2011*

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2008 Nov;74(11):1088-93. *Oral Presentation at Southern California Chapter ACS 2007 Annual Meeting.*

51. **Backhus LM**, Sievers EM, Lin Y, Castanos R, Bart RD, Starnes VA, Bremner RM. Peri-operative COX-2 inhibition reduces tumor cell adhesion and metastatic potential of circulating tumor cells in NSCLC. *J Thorac Cardiovasc Surg*. 2006 Aug;132(2):297-303. *Oral Presentation at WTSA 2005 Annual Meeting.*

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53. **Backhus LM**, Sievers EM, Schenkel FA, Barr ML, Cohen RG, Smith M, Starnes VA, Bremner RM. Pleural Space Problems Following Living Lobar Transplantation. *J Heart Lung Transplant*. 2005 Dec;24(12):2086-90. *Poster Presented at CHEST 2004 Annual Meeting.*

54. **Fuller, LM**, Huprich J, Theisen J, Hagen J, Crookes P, DeMeester T, DeMeester S, Bremner C, Peters J. Abnormal esophageal body function: radiographic-manometric correlation. *Am Surg.* 65(10):911-4, 1999 Oct. *Oral Presentation at the Southern California Chapter of the American College of Surgeons 1999 Annual Meeting.*

55. **Fuller, LM**, Maio W, Mackic J, Zlokovic B. Blood brain barrier transport of amyloid beta peptides. *J of Investigative Medicine.* Jan 1998

Chapters:

1. Greenfield's Surgery : Scientific Principles and Practice; Chapter: Esophageal Tumors and Injury. Lui N, Berry M, Zak Y, **Backhus L**. editors, Michael W. Mulholland et al, with 216 contributors ; illustrations by Holly R. Fischer.. Philadelphia, PA :Lippincott Williams & Wilkins, 7th Ed. 2021

2. Oyetunji S, **Backhus L**. "Esophagus" In: *Surgery Review Illustrated*. Eds. McElroy LM and Webb TP. McGraw-Hill, New York, NY (in press)

3. **Backhus LM**, Cheng AM, Wood DE. “Endoscopic Diagnosis of Thoracic Disease.” In: *Sabiston and Spencer’s Surgery of the Chest*, 9th Edition, Volume 1. Eds. Sellke F, del Nido PJ, Swanson SJ. Elsevier Health Sciences, 2015.

4. **Backhus LM**, Grochowski Z, Mulligan MS, Kuzdzal J, Wood DE. “Bronchoscopic Management of Airway Obstruction.” in *The European Society of Thoracic Surgeons Textbook of Thoracic Surgery*, Volume 1. Ed. Jaroslaw Kuzdzal. Krakow: Medycyna Praktyczna, 2014. 406-419.

5. **Backhus LM**, Varghese TK, Mulligan MS. "Lung Volume Reduction Surgery." in *The European Society of Thoracic Surgeons Textbook of Thoracic Surgery*, Volume 1. Ed. Jaroslaw Kuzdzal. Krakow: Medycyna Praktyczna, 2014. 1048-1054.

6. **Backhus LM**, Bremner RM. "pH & bilirubin monitoring." *Shackelford's Surgery of the Alimentary Tract,* 6th Edition. Volume I. Eds Richard Shackelford, Charles Yeo, Jeffrey Peters. Philadelphia: Saunders, c2007.

Other Media (Podcasts/Webinars):

1. **Backhus LM**. Invited Speaker. "Lung Cancer in Women". The National Lung Cancer Roundtable. American College of Radiology Webinar. Original Air Date: Nov 3, 2021.

2. **Backhus LM**. Invited Speaker. "Women in Cardiothoracic Surgery: A Global Perspective". AIS Channel. Webinar. Original Air Date: Oct 26, 2021. https://aischannel.com/live-surgery/women-in-cardiothoracic-surgery-a-global-perspective/

3. **Backhus LM**. Invited Speaker. "The Historical Relationship Between Black America, Medicine, and Research: Deconstructing Barriers and Optimizing Care". Audible Bleeding Podcast; Original Air Date: July 11, 2021. https://www.audiblebleeding.com/black-america-and-vascular-surgery/

4. **Backhus LM.** Invited Speaker. "Women in Thoracic Surgery Scholarship: Impact on Career Path and Interest in Cardiothoracic Surgery." STS Hot Topics Podcast; Original Air Date: July 30, 2021. https://www.podbean.com/ew/pb-e96qc-10a052d

5. **Backhus LM.** Invited Speaker. Episode 06: "How High-Achieving Moms Balance Career and Family: The 6% with Nancy MD Podcast. https://www.nancymd.com/podcasts/leahbackhusmd/.

6. **Backhus LM**. Invited Speaker. "Helping Women Surgeons Build Resiliency: Virtual Event Shares Experience and Insights". Johnson & Johnson Institute. Original Air Date: Aug 4, 2020. https://jnjinstitute.com/en-us/news/helping-women-surgeons-build-resiliency-virtual-event-shares-experience-and-insights.

7. Baiu I, **Backhus L**. Esophageal Cancer Surgery. *JAMA*. 2020 Oct 20;324(15):1580. doi: 10.1001/jama.2020.2101.

3. Baiu I, **Backhus L**. What Is a Tracheostomy? *JAMA*. 2019 Nov 19;322(19):1932. doi: 10.1001/jama.2019.14994. PMID:31742632

4. **Backhus LM**. Invited Speaker. "Safety and Gender Inclusion in Cardiothoracic Surgery." STS Hot Topics Podcast: https://www.sts.org/publications/podcast-episodes. 2018 Dec

5. **Backhus, LM.** Society of Thoracic Surgeons Patient Education Web Publication. "*From Maximal to Minimal in Thoracic Surgery: Less is More…but not Always*". http://ctsurgerypatients.org/

Exhibit B

Official Copy

STANFORD HOSPITAL 500P
500 PASTEUR DR
PALO ALTO CA 94305-2200

Hernandez-Valdez, Anthony Michael
MRN: 36945558, DOB: 9/23/1998, Sex: M
Adm: 2/12/2022

Consults by Rodriguez, Fatima, MD at 2/13/2022 7:43 PM (continued)

I saw and examined the patient and discussed management with the resident.I reviewed the resident's note and agree with the documented findings and plan of care, with the addition and/or exception of the items documented below:

Impression and Plan: Patient is not in clinical tamponade. Review of his echocardiogram shows a small to moderate loculated effusion. There is underlying constrictive physiology from mesothelioma with the pericardial involvement. No current indication for any cardiovascular interventions. Patient awaiting plan from oncology for mesothelioma treatment.

Time in Counseling and Coordination
The following is only applicable if counseling or coordination time with patient and/or family (C) is >50% of total attending floor/unit time including face to face time with patient and/or family (V).
Not Applicable

Fatima Rodriguez, MD

Electronically signed by Rodriguez, Fatima, MD at 2/13/2022 9:05 PM

H&P by Backhus, Leah Monique, MD at 2/14/2022 11:14 AM

Author: Backhus, Leah Monique, MD | Service: Thoracic Surgery | Author Type: Physician
Filed: 2/16/2022 12:31 AM | Date of Service: 2/14/2022 11:14 AM | Note Type: H&P
Status: Addendum | Editor: Backhus, Leah Monique, MD (Physician)
Related Notes: Original Note by Anderson, Taylor, MD (Resident) filed at 2/15/2022 7:52 AM

Stanford Hospital and Clinics
Thoracic Surgery Consult H&P

Service: Treatment Team: Tt, Med Oncology - Mix Surge Team C **Attending:** Cao, Michelle Thi, DO **Referring provider**: Selfreferral **Patient's Name/MRN:** Anthony Michael Hernandez-Valdez, 36945558	**Admit Date:**2/12/2022 **Today's Date:** 2/14/2022 **Length of stay:** LOS: 2 days **Room #:** E344/E344A

Reason for consult: pericardial epithelioid mesothelioma

HPI: Anthony Michael Hernandez-Valdez is a 23 Y male with a history of newly diagnosed pericardial epithelioid mesothelioma c/b malignant pericardial and pleural effusions and constrictive pericarditis (EF 49%).

Patient originally presented in 2020 with a persistent cough and pericardial resolution that failed to respond to multiple courses of colchine and prednisone over the past 2

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H&P by Backhus, Leah Monique, MD at 2/14/2022 11:14 AM (continued)

years.

1/4/2022: Presented with progressive cervical adenopathy and workup demonstrating pericardial mass, worsening pericardial effusion, and small pleural effusions.

1/10/22: Underwent right paratracheal (R4) lymph node biopsy. Path revealed mesothelioma, epithelioid type.

1/20-1/24 Admitted for dyspnea, found to have pulmonary embolism, started on apixaban.
1/24 Echo demonstrating constrictive-effusive pericarditis with EF 49%

1/28: Oncology outpatient visit, referred for thoracic evaluation.

2/6-2/9: Admitted with dyspnea and large bilateral pulmonary effusions, underwent bilateral thoracentesis (R 2/8, L 2/9) with removal of 1.5L fluid from each side.
2/8: PET scan showing extensive nodular hypermetabolic thickening of pericardium and Widespread mediastinal adenopathy extending into the cardiophrenic angle and retroperitoneum, and supraclavicular areas.

2/12: Readmitted with SOB, chest pressure, tachycardia to 200s. CTPE on 2/12 showing nodular pericardial thickening and negative for PE. Notable laboratory values: Wbc 7.5, Hgb 12, platelet 348, Cr 0.87, INR 1.4.

Patient remains persistently tachycardic and reports ongoing dyspnea especially with exertion, persistent food regurgitation that has improved since hospitalization, body aches, and nonproductive cough. Denies orthopnea, hemoptysis, unintentional weight loss.

Past Medical History:

Past Medical History:

Diagnosis	Date
• Mesothelioma (CMS-HCC)	
• Pericardial effusion	
• Pleural effusion, malignant	
• Pulmonary embolism (CMS-HCC)	
appendicitis	

Past Surgical History:

Appendectomy (2009)

Allergies:

Allergies

Allergen	Reactions
• Zofran [Ondansetron Hcl]	Nausea, Vomiting, Dizziness and

Family History: His family history is not on file.

Social History:
Social EtOH
No drug use
Father in construction, younger sibling at home

Review of Systems
Pertinent items are noted in HPI. A complete review of systems was otherwise negative.

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H&P by Backhus, Leah Monique, MD at 2/14/2022 11:14 AM (continued)

Headache

Medications:

Current Facility-Administered Medications:
- acetaminophen (Tylenol) tablet 650 mg, 650 mg, Oral, Q6H PRN, Cao, Michelle Thi, DO, 650 mg at 02/14/22 1807
- ALPRAZolam (Xanax) tablet 0.25 mg, 0.25 mg, Oral, TID PRN, Cao, Michelle Thi, DO, 0.25 mg at 02/14/22 1045
- benzonatate (Tessalon) capsule 100 mg, 100 mg, Oral, Q4H PRN, Cao, Michelle Thi, DO, 100 mg at 02/14/22 1016
- enoxaparin (Lovenox) syringe 120 mg, 120 mg, Subcutaneous, Q12H, Dobos, Katharine Marie, MD, 120 mg at 02/14/22 2116
- hydrOXYzine HCL (Atarax) tablet 25 mg, 25 mg, Oral, Q8H PRN, Cao, Michelle Thi, DO, 25 mg at 02/13/22 1504
- LR IV infusion, , Intravenous, Continuous, Cao, Michelle Thi, DO, Last Rate: 75 mL/hr at 02/15/22 0039, New Bag at 02/15/22 0039
- melatonin tablet 3 mg, 3 mg, Oral, QHS PRN, Cao, Michelle Thi, DO
- oxyCODONE (Roxicodone) tablet 5 mg, 5 mg, Oral, Q4H PRN, Cao, Michelle Thi, DO
- pantoprazole (Protonix) delayed release tablet 40 mg, 40 mg, Oral, QAM AC, Cao, Michelle Thi, DO, 40 mg at 02/15/22 0544
- prochlorperazine (Compazine) tablet 10 mg, 10 mg, Oral, Q6H PRN, Cao, Michelle Thi, DO

Physical Exam
VITAL SIGNS:
Visit Vitals

BP	116/87
Pulse	117
Temp	37.1 °C (98.7 °F) (Oral)
Resp	20
Ht	1.854 m (6' 1")
Wt	114 kg (251 lb 5.2 oz)
SpO2	96%
BMI	33.16 kg/m²

GENERAL: sitting in bed comfortably in NADH
HEENT: no palpable cervical or supraclavicular lymphadenopathy

H&P by Backhus, Leah Monique, MD at 2/14/2022 11:14 AM (continued)

CHEST AND LUNGS: normal work of breathing on RA, O2 sat >96%, bibasilar diminished lung sounds, no wheezes or crackles noted
CARDIOVASCULAR: tachycardic, regular rhythm per monitor
EXTREMITIES: moving spontaneously
NEURO: Alert and oriented

Labs:

CBC:
Recent Labs

	02/12/22 1423	02/13/22 0728	02/14/22 0551
WBC	8.2	8.8	7.6
HGB	**12.8***	**12.4***	**12.0***
HCT	41.1	40.2	**39.7***
PLT	328	325	348

LFTs:
Recent Labs

	02/12/22 1423
TBIL	0.9
AST	19
ALT	20
ALKP	**154***
ALB	3.6

Coags:
Recent Labs

	02/12/22 1623
PT	**17.2***
INR	**1.4***

Electrolytes:
Recent Labs

	02/12/22 1423	02/13/22 0728	02/14/22 0551
NA	**134***	**133***	138
K	3.8	4.0	4.1
CL	100	101	104
CO2	22	22	22
BUN	10	11	9
CR	0.87	0.86	0.87
CA	8.5	8.4	**8.3***

Blood glucose:
Recent Labs

	02/12/22 1423	02/13/22 0728	02/14/22 0551
GLU	96	98	88

No results for input(s): LIPASE, AMYLASE, LAC, LDH in the last 72 hours.

UA:
No results for input(s): UCOL, SPG, UGLU, UKET, UBLOOD, UPH, UPROT, NITRITE, LEUKEST, URBC, UWBC, UBACT, SQEP, MUCUS, UCMT in the last 72 hours.

Imaging:

CT Chest Angiography w IV Contrast Pulmonary Embolism

Result Date: 2/12/2022
IMPRESSION: 1. No evidence of pulmonary embolism.. 2. History of mesothelioma. Again seen is nodular pericardial thickening and moderate effusion with extensive mediastinal and cardiophrenic lymphadenopathy. 3. Bilateral moderate pleural effusions with associated compressive atelectasis. Additional areas of groundglass opacities and nodular consolidations involving the left lower lobe are likely representing airspace opacities. There are no substantial differences between the preliminary results and the impressions in this final report. I have personally reviewed the images for this examination and agree with the report transcribed above. Signed"Final report"

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H&P by Backhus, Leah Monique, MD at 2/14/2022 11:14 AM (continued)

XR Chest 1 View

Result Date: 2/12/2022
IMPRESSION: 1. Retrocardiac opacity may reflect atelectasis versus aspiration/infection. 2. Persistent moderate left pleural effusion There are no substantial differences between the preliminary results and the impressions in this final report. I have personally reviewed the images for this examination and agree with the report transcribed above. Signed"Final report"

Assessment/Recommendation:
Anthony Michael Hernandez-Valdez is a 23 Y male with a history of newly diagnosed pericardial epithelioid mesothelioma c/b malignant pericardial and pleural effusions and constrictive pericarditis.

Patient presents with symptomatic rapid reaccumulation of malignant pleural effusions s/p recent thoracentesis and would benefit from additional drainage, with indication for long-term pleurx catheter placement given likelihood of recurrence. Overall poor prognosis with advanced local disease, supraclavicular and retroperitoneal lymphadenopathy. Recommend additional discussion with medical oncology for initiation of chemotherapy as well as consult to cardiac surgery for consideration of pericardiectomy as means of surgical debulking given evidence of hemodynamically significant constrictive-effusive pericarditis. These measures are temporizing given advanced disease, recommend additional discussion with patient and family to determine goals and appropriate course of care.

Recommendations:
- **Obtain cardiac MRI for preoperative workup**
- **Pleurx catheter placement for long-term management of malignant effusions**
- **Consult to medical oncology**
- **Consult to cardiac surgery for pericardiectomy consideration**
- **Goals of care discussion with family and patient. Thoracic surgery to remain available for involvement in this discussion if needed.**

This patient was discussed with Dr. Backhus, attending surgeon, who agreed with the above assesment and plan.

Taylor Anderson, MD
Thoracic Surgery, p12060
11:20 AM 2/14/2022

ATTENDING ATTESTATION:
I personally saw and evaluated the patient, and participated in the management and treatment plan as documented in the above note. The patient was seen at bedside along with his mother. All imaging were reviewed personally. Overall, primary pericardial mesothelioma is an extremely rare condition with a poor

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H&P by Backhus, Leah Monique, MD at 2/14/2022 11:14 AM (continued)

prognosis. Most often these are refractory to traditional chemotherapy regimens. Mainstay of therapy is surgical debulking primarily for palliation of effusions and relief of constrictive pericarditis. The latter is an extensive undertaking so goals of care must be clear. I emphasized this to him and his mother. He also has extensive adenopathy which underscores the advanced stage of his disease. Per my review, however and given his young age and functional status, surgery should be considered followed by adjuvant chemotherapy at the discretion of medical oncology. To that end, I have already discussed his case with Dr Boyd from Cardiac Surgery to provide an assessment of operability from his perspective. If he agrees, this can be done as a joint case. I can address his effusions, provide lymph node dissection for the mediastinal nodes accessible via median sternotomy approach as well as potentially address any visible pleural lesions. I can also place pleur-x catheters for longterm management of his pleural effusions. Will follow up with Cardiac Surgery and Medical Oncology to determine feasibility of this plan. I spent a total of > 60 min in direct patient evaluation and care coordination among providers for this encounter. He and his mother asked several insightful questions and they are agreeable with this tentative plan.

Electronically signed by Backhus, Leah Monique, MD at 2/16/2022 12:31 AM

H&P by Shieh, Tim Han, PA at 2/15/2022 12:30 AM

Author: Shieh, Tim Han, PA | Service: Cardiac Surgery | Author Type: Physician Assistant
Filed: 2/15/2022 1:21 AM | Date of Service: 2/15/2022 12:30 AM | Note Type: H&P
Status: Signed | Editor: Shieh, Tim Han, PA (Physician Assistant)
Cosigner: Boyd, Jack H, MD at 2/24/2022 1:31 PM

Stanford Hospital and Clinics
Cardiac Surgery History and Physical

Date: 2/15/2022 Service: Cardiac Surgery Attending: Jack H. Boyd, M.D.

ALLERGIES:
- sensitivity to ondansetron (nausea, headache)

History of Present Illness:
Anthony Hernandez-Valdez is a pleasant 23 year old male with a past medical history of appendicitis status post appendectomy circa 2009 and COVID+ 1/20, with a recent diagnosis of epithelioid mesothelioma, who presented to the hospital with a c/c of dyspnea and was found to have pulmonary edema and worsening

Exhibit C

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H&P by Shieh, Tim Han, PA at 2/15/2022 12:30 AM (continued)

Recent Labs

	02/14/22 0551
Sodium, Ser/Plas	138
Potassium, Ser/Plas	4.1

Diabetes :
Hematologic :
Nutrition : per dietitian:
BMI from flowsheet: 33.2

Malignancy : Primary malignancy of lungs (site) Confirmed
Functional Status :

Tim Shieh, PA-C
Cardiothoracic Surgery

Electronically signed by Boyd, Jack H, MD at 2/24/2022 1:31 PM

Operative Report signed by Boyd, Jack H, MD at 3/8/2022 4:57 PM

Author: Boyd, Jack H, MD | Service: Cardiac Surgery | Author Type: Physician
Filed: 3/8/2022 4:57 PM | Date of Service: 2/17/2022 6:00 PM | Note Type: Operative Report
Status: Signed | Editor: Boyd, Jack H, MD (Physician)

DATE OF OPERATION: 02/17/2022

PREOPERATIVE DIAGNOSES:
1. Pericardial mesothelioma.
2. Bilateral pleural effusions.
3. Pericardial constriction.

POSTOPERATIVE DIAGNOSES:
1. Pericardial mesothelioma.
2. Bilateral pleural effusions.
3. Pericardial constriction.

OPERATION PERFORMED:
1. Pericardiectomy (33030).
2. Bilateral PleurX catheters performed by Dr. Backhus.
3. Resection of mediastinal mass performed by Dr. Backhus.

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Operative Report signed by Boyd, Jack H, MD at 3/8/2022 4:57 PM (continued)

SURGEON: Jack H Boyd, MD

SURGEON: Leah M Backhus, MD.

CO-SURGEON: Jack H Boyd, MD.

SURGERY RESIDENT: Irmina A Elliott, MD

ASSISTANT: Jessica C Warner, PA-C

INTRAOPERATIVE FINDINGS:
1. Large bilateral chylothoraces.
2. Diffuse tumor involvement of the pericardium with areas of invasion into the myocardium.

INDICATION FOR SURGERY: Anthony Hernandez is a 23-year-old male with the above diagnoses. He has been offered palliative pericardiectomy and mass excision as well as PleurX catheter placement. The risks, benefits, and alternatives were discussed. All questions were answered. Informed consent was obtained.

DESCRIPTION OF PROCEDURE: Please refer to Dr. Backhus' separate note for her portions of the procedure.

The patient was brought to the operating room, placed in the supine position on the operating table. Femoral lines were placed, and then general anesthesia was induced. The patient was intubated and the appropriate monitoring lines and catheters were placed. The patient was then prepped and draped in normal sterile fashion. A median sternotomy was performed. Both pleural spaces were opened widely and large quantities of chylous effusion were removed by suction approximately 5-6 L in total. We then began by excising all the mediastinal fat and then attempted to open the pericardium in several places before finding an area overlying the right ventricle. We then slowly removed after identifying the proper plane, removed as much pericardium as we could from around the right atrium over the right ventricle and out toward the left ventricular apex. There were areas of direct tumor involvement into the heart and these areas were spared. All in all from nearly right phrenic to the left phrenic with about 2 cm on either side from the level of the diaphragm up to the aorta the vast majority of the pericardium with tumor involved was resected. After completing the pericardiectomy and a thymectomy with other mediastinal fat excision by Dr. Backhus, it was determined this should complete the extent of our resection. During the surgery, the patient's CVP decreased from the high 20s to low 20s. The pulmonary pressures dropped nearly in half from a

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Operative Report signed by Boyd, Jack H, MD at 3/8/2022 4:57 PM (continued)

systolic of 60 to a systolic in the low 30s and the cardiac output doubled. Drainage catheters were placed. Dr. Backhus and her team placed PleurX catheters and the chest wall was closed in the standard fashion. Needle, sponge, and instrument counts were correct. Pre and postoperative time-outs were performed. I was present and scrubbed for the procedure.

Jack H Boyd, MD

CC: Han Zhu, MD

Fatima Rodriguez, MD

Mohana Roy, MD

D: 02/18/2022 13:30:53 T: 02/18/2022 14:02:56 / MODL
SJN: 947455498 DJN: 354233

Electronically signed by Boyd, Jack H, MD at 3/8/2022 4:57 PM

Operative Report by Backhus, Leah Monique, MD at 2/17/2022 10:00 PM

Author: Backhus, Leah Monique, MD | Service: Thoracic Surgery | Author Type: Physician
Filed: 2/20/2022 5:27 PM | Date of Service: 2/17/2022 10:00 PM | Note Type: Operative Report
Status: Addendum | Editor: Backhus, Leah Monique, MD (Physician)
Related Notes: Original Note by Elliott, Irmina A, MD (Fellow) filed at 2/20/2022 12:34 PM

DATE OF OPERATION: 02/17/2022

PREOPERATIVE DIAGNOSES:
1. Pericardial mesothelioma.
2. Bilateral pleural effusions.
3. Pericardial constriction.

POSTOPERATIVE DIAGNOSES:
1. Pericardial mesothelioma.
2. Bilateral pleural effusions, chylothoraces.
3. Pericardial constriction.

OPERATION PERFORMED:
1. Pericardiectomy (performed by Dr. Boyd)
2. Bilateral PleurX catheters

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Operative Report by Backhus, Leah Monique, MD at 2/17/2022 10:00 PM (continued)

3. Resection of mediastinal mass and thymectomy

SURGEON: Leah M Backhus, MD.
CO-SURGEON: Jack H Boyd, MD.

SURGERY RESIDENT: Irmina A Elliott, MD

ASSISTANT: Jessica C Warner, PA-C

INTRAOPERATIVE FINDINGS:
1. Large bilateral chylothoraces.
2. Diffuse tumor involvement of the pericardium with areas of invasion into the myocardium.

INDICATION FOR SURGERY: Anthony Hernandez is a 23-year-old male with pericardial mesothelioma. He has been offered palliative pericardiectomy for tumor debulking with the hope of relieving his shortness of breath as well as PleurX catheter placement. The risks, benefits, and alternatives were discussed. All questions were answered. Informed consent was obtained.

DESCRIPTION OF PROCEDURE: Please refer to Dr. Boyd's separate note for his portions of the procedure. The patient was brought to the operating room, placed in the supine position on the operating table. Before induction of general anesthesia, an ultrasound-guided sheath was placed in the left common femoral artery and right common femoral vein. General anesthesia was induced and the patient was then prepped and draped in the usual sterile fashion.

As indicated in Dr. Boyd's note, a median sternotomy was made. The pleural spaces were opened and what appeared grossly to be bilateral chylous effusions were evacuated totally 4-5 Liters of fluid. Partial pericardiectomy was performed. We then proceeded with thymectomy, dissecting the pericardial fat and thymus free from the pericardial surface from the level of the diaphragm to above the innominate vein, taking care not to injure the phrenic nerves. The draining thymic veins were ligated with clips and divided. Of note, the thymus and pericardial fat were nodular and thickened, containing areas of tumor. We then placed bilateral tunneled PleurX catheters. Incisions were made at appropriate exit sites, and the catheters positioned using the tunneler with the cuff just within the exit incision. We also placed bilateral straight chest tubes and a mediastinal tube.

The chest wall was closed in the standard fashion. Needle, sponge, and instrument counts were correct. Pre and postoperative time-outs were performed.

Surgical Teaching Physician Attestation
I was present, scrubbed and directly participated in the entire surgical procedure detailed above.

Leah Monique Backhus, MD
Thoracic Surgery

Electronically signed by Backhus, Leah Monique, MD at 2/20/2022 5:27 PM

Documentation Clarification by Novack, Michael Raedy, MD at 2/18/2022 10:29 AM

Exhibit D

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Stanford HEALTH CARE STANFORD MEDICINE

CANCER CENTER SOUTH BAY
2589 SAMARITAN DR
SAN JOSE CA 95124-3908

Hernandez-Valdez, Anthony Michael
MRN: 36945558, DOB: 9/23/1998, Sex: M
Visit date: 3/14/2022

Progress Notes by Roy, Mohana, MD at 3/14/2022 1:00 PM (continued)

-Using Lorazepam 1 mg as needed

#Cardiac Management-in discussing the case with Dr. Boyd and Dr. Backus and reviewing the operative reports, he has still significant mesothelial tumor involvement around his heart and some into the myocardium. Recommend continuing metoprolol succinate 75 mg daily.
-Repeat ECHO
-off colchicine

#Thrombosis - non occlusive thrombus bilateral internal jugular and left brachiocephalic veins
#Right subsegmental PE:
He is still on rivaroxaban 15 mg daily with the initial loading. And will transition to 20 mg daily.
-can consider anti-XA level if worried about DOAC inefficacy

 # Acid reflux
 # Nausea
- Continue compazine as needed
-Continue Pepcid twice a day

RTC scheduled 3/18/22

As usual, I encouraged the patient to contact us should he develop any new symptoms or have any questions or concerns

Mohana Roy, MD
Clinical Assistant Professor-Oncology
Stanford Cancer Center Palo Alto and South Bay

Electronically signed by Roy, Mohana, MD at 3/15/2022 9:23 AM

Progress Notes by Roy, Mohana, MD at 3/18/2022 9:00 AM

Author: Roy, Mohana, MD | Service: Oncology | Author Type: Physician
Filed: 3/29/2022 8:13 AM | Encounter Date: 3/18/2022 | Note Type: Progress Notes
Status: Addendum | Editor: Roy, Mohana, MD (Physician)
Related Notes: Original Note by Roy, Mohana, MD (Physician) filed at 3/19/2022 11:12 AM

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Stanford Thoracic Oncology Clinic
Return Patient Visit
Palo Alto

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STANFORD ADVANCED MEDICINE CENTER
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Hernandez-Valdez, Anthony Michael
MRN: 36945558, DOB: 9/23/1998, Sex: M
Visit date: 3/18/2022

Progress Notes by Roy, Mohana, MD at 3/18/2022 9:00 AM (continued)

RE:
Dr. Leah Backhus
Dr. Han Zhu
Dr. Josh Fronk

MRN: 36945558
DOB: 9/23/1998

History of present illness:
Anthony Michael Hernandez-Valdez is a 23 Y old male who was recently diagnosed with epithelioid mesothelioma, suspect pericardial primary, here for followup after hospitalization and pericardiectomy

His oncologic history is summarized as follows:

2020: Developed cough and shortness of breath. Had been admitted with several echocardiograms performed, which showed pericardial effusions. Has only been treated on colchicine and prednisone.

1/4/22: Developed worsening adenopathy and neck swelling and underwent a CT neck for left sided neck swelling. Imaging revealed abnormal shotty appearing lymph nodes along the left neck and left neck soft tissue spaces including the left jugulodigastric which is enlarged measuring 1.3 cm. Numerous posterior cervical lymph nodes and bilateral supraclavicular lymph nodes.

CT chest revealed worsening lobulated masslike pericardial effusion. Worsening multiple enlarged neck soft tissue lymph nodes and subcutaneous soft tissue edema extending through the chest wall to level of the trachea. Notable supraclavicular, mediastinal, and retroperitoneal lymphadenopathy. Small pleural effusion.

1/10/22: Underwent right paratracheal (R4) lymph node biopsy. Path revealed mesothelioma, epithelioid type.

1/28/2022: **Initial Thoracic Oncology Visit (Roy)**

1/31/22: AFP, LDH, beta HCG, uric acid levels are wnl.

2/3/22: Scrotal ultrasound is negative.

2/6/22- SHC admission for shortness of breath-initially relieved by 2 thoracentesis with 1-1/2 L taken out on each side. Pleural fluid confirms malignant cells, morphologically similar to mesothelioma.

2/12/-2/22/22-SHC readmission with worsening respiratory status, concern for right-sided heart failure and will remain tachycardic.
He underwent **Pericardiectomy (performed by local Dr. Boyd) Bilateral PleurX catheters, Resection of mediastinal mass and thymectomy on 2/17/22**
OPERATIVE FINDINGS:
1. Large bilateral chylothoraces.
2. Diffuse tumor involvement of the pericardium with areas of invasion into the myocardium

3/18/22 CT Chest- Similar to 2/26/2022, **multiple pericardial masses nearly encasing the heart, thoracic lymphadenopathy, retrocrural lymphadenopathy**, and adjacent right upper lobe and right middle lobe

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Hernandez-Valdez, Anthony Michael
MRN: 36945558, DOB: 9/23/1998, Sex: M
Visit date: 3/18/2022

Progress Notes by Roy, Mohana, MD at 3/18/2022 9:00 AM (continued)

interlobular septal thickening, concerning for residual/recurrent malignancy. Interlobular septal thickening may represent lymphangitic carcinomatosis versus lymphatic obstruction. Interval increase in extensive filling defects throughout the venous system, including left internal jugular, left brachiocephalic, right internal jugular, right brachiocephalic, and right vertebral veins. No evidence of extension of the thrombus into the superior vena cava

Interval History
He is feeling okay overall
He had SOB and feeling unwell after taking dexamethasone 4 mg yesterday
He continues to drain 1 L on each side with the Pleurx catheter every day- slight decrease seen on right side
No otherwise SOB, palpitations, chest pain
Still having issues in having adequate drainage supplies - pictures of drainage with white milky fluid

Review of systems:
A comprehensive 14-point review of systems was performed, with pertinent positives as noted above; all other systems negative.

Past medical history:
Anxiety
Appendicitis

Past surgical history:
Past Surgical History:

Procedure	Laterality	Date
• BILATERAL PROCEDURE; SECONDARY MODIFIER *Performed by Backhus, Leah Monique, MD at STANFORD HOSPITAL 500P INTERVENTIONAL PLATFORM*	N/A	2/17/2022
• CHEST DRAINAGE CATHETER INSERTION *Performed by Backhus, Leah Monique, MD at STANFORD HOSPITAL 500P INTERVENTIONAL PLATFORM*	Bilateral	2/17/2022
• MEDIASTINAL LYMPHADENECTOMY, BILATERAL TUNNELED PLEURAL CATHETERS (PLEUR-X), POSSIBLE PLEURECTOMY, RADICAL PERICARDIECTOMY, THYMECTOMY WITH CPB STANDBY *Performed by Boyd, Jack H, MD at STANFORD HOSPITAL 500P INTERVENTIONAL PLATFORM*	N/A	2/17/2022
• THYMECTOMY; MEDIAN STERNOTOMY APPROACH *Performed by Backhus, Leah Monique, MD at STANFORD HOSPITAL 500P INTERVENTIONAL PLATFORM*	N/A	2/17/2022

Appendectomy 2009

Medications:
Outpatient Medications Prior to Visit

Medication	Sig	Dispense	Refill
• acetaminophen (TylenoL) 325 mg TABS	take 2 Tablets by mouth 2 times a day as needed		
• Cholecalciferol (Vitamin D3)	take 1 Capsule by		

Progress Notes by Roy, Mohana, MD at 3/18/2022 9:00 AM (continued)

(Vitamin D3) 2,000 unit CAPS	mouth every day		
• Cyanocobalamin 1,000 mcg SUBL	place 1 Tablet under the tongue and let dissolve every day		
• dexAMETHasone (Decadron) 4 mg tablet	take 1 Tablet (4 mg total) by mouth as directed Take once daily on the day before, the day of and the day after pemetrexed (ALIMTA).	30 Tablet	2
• famotidine (Pepcid) 20 mg tablet	take 1 Tablet (20 mg total) by mouth 2 times a day	60 Tablet	0
• LORazepam (Ativan) 1 mg tablet	take 1 Tablet (1 mg total) by mouth every 8 hours as needed	30 Tablet	0
• metoprolol succinate (Toprol XL) 50 mg extended release tablet	take 2 Tablets (100 mg total) by mouth daily	90 Tablet	3
• octreotide (SandoSTATIN) 100 mcg/mL injection	inject 1 mL (100 mcg total) subcutaneous (under the skin) every 8 hours	90 Vial	0
• ondansetron 8 mg tablet	take 1 Tablet (8 mg total) by mouth every 8 hours as needed For nausea and vomiting	30 Tablet	5
• prochlorperazine (Compazine) 10 mg tablet	take 1 Tablet (10 mg total) by mouth every 8 hours as needed For nausea or vomiting	30 Tablet	5
• prochlorperazine (Compazine) 10 mg tablet	take 1 Tablet (10 mg total) by mouth every 6 hours as needed for Nausea/Vomiting	30 Tablet	3
• rivaroxaban (Xarelto) 20 mg TABS	take 20 mg by mouth daily (Start after finishing 21 days of Xarelto 15 mg twice daily)		

No facility-administered medications prior to visit.

Allergies:

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Progress Notes by Roy, Mohana, MD at 3/18/2022 9:00 AM (continued)

NKDA

Social history:
Father works in construction and may have exposures, however only started in the past couple of years
Previously attended school in an old building, no clear asbestos exposure
Mother reports using large amounts of baby powder (Johnson and Johnson) in his childhood
No other exposures to hair salon products, chemicals in labs
Works at Home Depot
EtOH socially
No recreational drug use

Family history:
Father had ?bone cancer
Maternal aunt had early age breast cancer (diagnosed at age 33) and AML (diagnosed 35)

BRCA mutation:
- Mother, maternal grandmother, maternal aunts x 2

Physical Exam:
Filed Vitals:

	03/18/22 0958
BP:	118/66
Pulse:	115
SpO2:	98%
Weight:	102.9 kg (226 lb 13.7 oz)

General: Well-appearing and speaking in full sentences
CV: tachycardic, regular rhythm
Lungs: decreased at bases bilaterally
Abdomen: healed sternotomy scar, inspected both his drain sites which are overall clean and intact, the one on the left does have slightly increased granulation tissue
Extremities- without edema

Labs and studies:
Reviewed in epic, white count 11.3, hemoglobin is stable at 12.9, sodium is getting lower at 129 and we will have to monitor that

+chylous fluid on pleural effusion

Imaging:
As in HPI
Most recent review in tumor board of CTA 2/26/22

Pathology:
2/25/22 Pericardiectomy Specimen Review

A. THYMUS PERICARDIAL FAT
B. PERICARDIUM AND TUMOR
DIAGNOSIS (MICROSCOPIC):

Official Copy

STANFORD ADVANCED MEDICINE CENTER
300 PASTEUR DRIVE
MC:5500
PALO ALTO CA 94305-2200

Progress Notes by Roy, Mohana, MD at 3/18/2022 9:00 AM (continued)

A. THYMUS AND PERICARDIAL FAT, EXCISION
-- P**ERICARDIAL TISSUE WITH MALIGNANT MESOTHELIOMA, EPITHELIOID TYPE**
-- METASTATIC MALIGNANT MESOTHELIOMA COMPLETELY REPLACING ONE LYMPH NODE (1/1)
-- **EXTENSIVE VENOUS AND LYMPHATIC INVOLVEMENT BY MALIGNANT MESOTHELIOMA**
-- INVOLUTED THYMIC TISSUE
B. HEART, PERICARDIUM AND TUMOR, EXCISION
-- MALIGNANT MESOTHELIOMA, EPITHELIOID TYPE
LIBERT/C. WANG/BERRY

COMMENT: We note the patient's recent diagnosis of metastatic malignant mesothelioma, epithelioid type (SHS-22-03759). The tumor present in the current resection specimen is morphologically similar.

Stanford Review
DIAGNOSIS:
LYMPH NODES. RIGHT LOWER PARATRACHEAL/4R, EXCISIONAL BIOPSY (1/10/22; 22MS-133)
-- HISTOLOGIC AND IMMUNOPHENOTYPIC FINDINGS SUPPORTING **METASTATIC MALIGNANT MESOTHELIOMA, EPITHELIOID TYPE.**

COMMENT: I have reviewed the H&E stained slides and accompanying immunostains and agree with Dr. Silveira as listed above. In light of the unusual diagnosis in this age group I performed a battery of immunostains in our lab along with additional H&E stained slides. The neoplastic cells within the lymph node show the following immunophenotypic profile: **WT1 positive, P40 negative, CK5/6 positive, D2-40 positive, BAP1 retained, BerEP4 negative, calretinin positive, Claudin4 negative.** This supports metastatic malignant mesothelioma, epithelioid type. **The findings are consistent with pericardial origin.**

EBUS of 4R 1/10/22:

Immunostain for cytokeratin AE1/AE3, cytokeratin 7, and cytokeratin 5/6 are diffusely positive. Both calretinin and WT1 display nuclear staining of tumor. Ki-67 highlights around 25% of nuclei. Thrombomodulin stains tumor weakly (the external control stains no better). MOC31, BER-EP4, PAX8, thyroglobulin, CD5, p40, OCT-4, and CD117 are all negative. CD3/CD20 immunostain cocktail displays background aggregates of B cells, with surrounding T cells. Immunostain cocktail displays no nuclear uptake with TTF-1 and no cytoplasmic staining with napsin A.

Flow cytometry on tissue from part 2 was performed at NeoGenomics. Viability is poor (<50%) and most cells appear non-hematopoietic. Residual lymphocytes (11% of total) are primarily T cells (68%), with CD4/CD8 ratio of 1.6, and no loss of antigens. Please see appended report for additional details.

Molecular:

Official Copy

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300 PASTEUR DRIVE
MC:5500
PALO ALTO CA 94305-2200

Progress Notes by Roy, Mohana, MD at 3/18/2022 9:00 AM (continued)

2/4/22 Guardant peripheral- negative

STAMP 1/26/22

SUMMARY OF FINDINGS

Estimated tumor mutation burden: 3.0 mut/Mb†

The following variants are not known to be clinically relevant at this time:

ATR T1180A (Unknown significance)
TERT E441del (Unknown significance)
NTRK3 G642R (Unknown significance)

Please see the following pages for variant annotations.

Fusion STAMP pending

Assessment & Plan:
Anthony Michael Hernandez-Valdez is a 23 Y old male with newly diagnosed pericardial mesothelioma, status post pericardiectomy and Pleurx placement on 2/17/2022, here for follow-up and initiation of first cycle of chemotherapy.

#Epithelioid mesothelioma, pericardial-metastatic
We had previously discussed that this appears to be a primary mesothelioma of the pericardium which is exceedingly rare, even within the rare diagnosis of mesothelioma in general. In addition him being so young and age makes this additionally difficult.
-Today- starting C1D1 Carboplatin AUC 5, pemetrexed 375 mg/m² to be given for 4-6 cycles
-Emend given today but unfortunately he had a reaction to this in the infusion center- will avoid for future use
-Ativan 1 mg p.o. given baseline anxiety
-We will also avoid dexamethasone going forward unless needed given his reported reaction to it
-He will have cancer genetics consultation soon and as well as palliative care

#**Chylous Pleural Effusions-** discussed with Dr. Backhus-
-Continuing to drain Pleurx 1 L each side
-Plan to start octreotide 100 mics 3 times daily-he is concerned about giving himself the shot so we will circle back next week on timing of starting this pending how he is doing with chemotherapy

#Anxiety-baseline with coping of new diagnosis
Contacted Ms. Pam Simon in AYA group- for helping support him.
-Has upcoming initial consultation and meeting with Dr. Fronk in palliative care
-Using Lorazepam 1 mg as needed

#Cardiac Management-in discussing the case with Dr. Boyd and Dr. Backus and reviewing the operative reports, he has still significant mesothelial tumor involvement around his heart and some into the myocardium. Recommend continuing metoprolol succinate 75 mg daily.
-Repeat ECHO
-off colchicine

#Thrombosis - non occlusive thrombus bilateral internal jugular and left brachiocephalic veins-extension seen on recent CT, likely also due to impaired venous drainage from tumor burden
#Right subsegmental PE:
He is still on rivaroxaban 15 mg daily with the initial loading- and now on 20 mg daily.
-can consider anti-XA level if worried about DOAC inefficacy

Progress Notes by Roy, Mohana, MD at 3/18/2022 9:00 AM (continued)

 # Acid reflux
 # Nausea
- Continue compazine as needed
-Continue Pepcid twice a day

RTC scheduled for chemo cycles, will also request 1 week video visit check-in

As usual, I encouraged the patient to contact us should he develop any new symptoms or have any questions or concerns

Mohana Roy, MD
Clinical Assistant Professor-Oncology
Stanford Cancer Center Palo Alto and South Bay

Electronically signed by Roy, Mohana, MD at 3/29/2022 8:13 AM

Progress Notes by Thai, Quan B, NP at 3/18/2022 5:33 PM

Author: Thai, Quan B, NP | Service: Oncology | Author Type: Nurse Practitioner
Filed: 3/18/2022 6:05 PM | Date of Service: 3/18/2022 5:33 PM | Note Type: Progress Notes
Status: Addendum | Editor: Thai, Quan B, NP (Nurse Practitioner)
Related Notes: Original Note by Thai, Quan B, NP (Nurse Practitioner) filed at 3/18/2022 6:02 PM

Stanford Hospital and Clinics
ITA Sick Call Progress Note

Today's Date:3/18/2022
Attending Provider: Mohana Roy, MD
Patient's Name:Anthony Michael Hernandez-Valdez
Medical Record Number:36945558

Impression:
Anthony Michael Hernandez-Valdez is a 23 Y patient who has newly diagnosed ephithelioid mesothelioma, suspect pericardal primary s/p pericardiectomy who presents for C1 carboplatin/pemetrexed.

Reason for Sick Call APP assessment: Infusion reaction to fosaprepitant which was stopped and disconnected by infusion RN.

ROS:
- Pt developed throat tightening briefly, shortness of breath.
- Throat tightening resolved with stopping the infusion. Shortness of breath persisted.
- No flushing/rash/pruritis/rigors/fevers/CP

Exhibit E

Anthony Michael Hernandez-Valdez

Patient Health Summary, generated on May 19, 2022

Patient Demographics - Male; born Sep. 23, 1998

Patient Address	Communication	Language	Race / Ethnicity	Marital Status
2695 Agnes Way *(Home)* Merced, CA 95340-3133 *Former (Jan. 18, 2022 - Jan. 17, 2022):* 2695 Agness Way *(Home)* Merced, CA 95340 *Former (Mar. 07, 2017 - Jan. 17, 2022):* 2695 Agnes Way *(Home)* MERCED, CA 95340	[redacted]	English (Preferred)	Other Race / Hispanic or Latino	Single

Note from Stanford Health Care and University Healthcare Alliance

This document contains information that was shared with Anthony Michael Hernandez-Valdez. It may not contain the entire record from Stanford Health Care and University Healthcare Alliance.

Allergies

Fosaprepitant (Shortness of Breath)

Oxycodone (Itching, pruritis)

Ondansetron Hcl (Shortness of Breath, Nausea, Vomiting, Dizziness, Headache)

Patient Demographics - Male; born Sep. 23, 1998

Patient Address	Communication	Language	Race / Ethnicity	Marital Status
2695 Agnes Way *(Home)* Merced, CA 95340-3133 *Former (Jan. 18, 2022 - Jan. 17, 2022):* 2695 Agness Way *(Home)* Merced, CA 95340 *Former (Mar. 07, 2017 - Jan. 17, 2022):* 2695 Agnes Way *(Home)* MERCED, CA 95340	209-446-7294 (Mobile) 209-446-7294 (Home) emoryhernandez50@gmail.com	English (Preferred)	Other Race / Hispanic or Latino	Single

Note from Stanford Health Care and University Healthcare Alliance

This document contains information that was shared with Anthony Michael Hernandez-Valdez. It may not contain the entire record from Stanford Health Care and University Healthcare Alliance.

Reason for Visit

Follow Up (Routine) - Authorized

Specialty	Diagnoses / Procedures	Referred By Contact	Referred To Contact
Oncology	Diagnoses Mesothelioma, unspecified Pericardial effusion (noninflammatory)	Mohana Roy 2589 Samaritan Dr San Jose, CA 95124 Phone: (408)426-4900 Fax: 669-233-2482	Mohana Roy 2589 Samaritan Dr San Jose, CA 95124 Phone: (408)426-4900 Fax: 669-233-2482

Referral ID	Status	Reason	Start Date	Expiration Date	Visits Requested	Visits Authorized
15192665	Authorized		3/1/2022	2/28/2023	12	12

Encounter Details

Date	Type	Department	Care Team
05/06/2022	Telemedicine	Thoracic Oncology 875 Blake Wilbur Drive Palo Alto, CA 94305 650-498-6000	**Mohana Roy** 2589 Samaritan Dr San Jose, CA 95124 408-426-4900 (Work) 669-233-2482 (Fax)

Allergies - documented as of this encounter (statuses as of 05/19/2022)

Active Allergy	Reactions	Severity	Noted Date	Comments
Fosaprepitant	Shortness of Breath		03/18/2022	Throat tightness
Oxycodone	Itching, pruritis		02/26/2022	
Ondansetron Hcl	Shortness of Breath, Nausea, Vomiting, Dizziness, Headache		02/04/2022	Chest tightness

Active Problems - documented as of this encounter (statuses as of 05/19/2022)

Problem	Noted Date
Admission for antineoplastic chemotherapy	04/10/2022
Nausea and vomiting, unspecified vomiting type	04/10/2022
Nausea and vomiting	03/23/2022
Chylous effusion	03/15/2022
Pericardial effusion	02/12/2022
Dyspnea	02/06/2022
Pleural effusion	02/06/2022
Mesothelioma	01/30/2022

Resolved Problems - documented as of this encounter (statuses as of 05/19/2022)

Problem	Noted Date	Resolved Date
Shortness of breath	01/21/2022	01/23/2022

Immunizations - documented as of this encounter

Name	Administration Dates	Next Due
Flu vaccine (IIV4), preservative-free	01/24/2022	
Moderna COVID-19 Vaccine	05/21/2021, 04/23/2021	

Social History - documented as of this encounter

Tobacco Use	Types	Packs/Day	Years Used	Date
Never Smoker				
Smokeless Tobacco: Never Used				

Alcohol Use	Standard Drinks/Week
Not Currently	0 (1 standard drink = 0.6 oz pure alcohol)

Sex Assigned at Birth	Date Recorded
Not on file	

Job Start Date	Occupation	Industry
Not on file	Not on file	Not on file

Last Filed Vital Signs - documented in this encounter

Not on file

Ordered Prescriptions - documented in this encounter

Prescription	Sig	Dispensed	Start Date	End Date
LORazepam (Ativan) 1 mg tablet	take 1.5 Tablets (1.5 mg total) by mouth every 6 hours as needed	30 Tablet	05/06/2022	11/02/2022
pantoprazole (Protonix) 40 mg delayed release tablet	take 1 Tablet (40 mg total) by mouth daily	60 Tablet	05/06/2022	05/06/2023
famotidine (Pepcid) 40 mg tablet	take 1 Tablet (40 mg total) by mouth daily	60 Tablet	05/06/2022	05/17/2022

Progress Notes - documented in this encounter

Mohana Roy, MD - 05/06/2022 12:30 PM PDT

Formatting of this note is different from the original.
Images from the original note were not included.

Stanford Thoracic Oncology Clinic
Return Patient Visit
Palo Alto

Telemedicine: I have discussed the risks, benefits, and limitations of receiving care virtually with the patient. The patient expresses understanding and is willing to move forward.

MRN: 36945558
DOB: 9/23/1998

History of present illness:
Anthony Michael Hernandez-Valdez is a 23 Y old male who was recently diagnosed with epithelioid mesothelioma, suspect pericardial primary, on carboplatin and pemetrexed, here for followup

His oncologic history is summarized as follows:

2020: Developed cough and shortness of breath. Had been admitted with several echocardiograms performed, which showed pericardial effusions. Has only been treated on colchicine and prednisone.

1/4/22: Developed worsening adenopathy and neck swelling and underwent a CT neck for left sided neck swelling. Imaging revealed abnormal shotty appearing lymph nodes along the left neck and left neck soft tissue spaces including the left jugulodigastric which is enlarged measuring 1.3 cm. Numerous posterior cervical lymph nodes and bilateral supraclavicular lymph nodes.

CT chest revealed worsening lobulated masslike pericardial effusion. Worsening multiple enlarged neck soft tissue lymph nodes and subcutaneous soft tissue edema extending through the chest wall to level of the trachea. Notable supraclavicular, mediastinal, and retroperitoneal lymphadenopathy. Small pleural effusion.

1/10/22: Underwent right paratracheal (R4) lymph node biopsy. Path revealed mesothelioma, epithelioid type.

1/28/2022: Initial Thoracic Oncology Visit (Roy)

1/31/22: AFP, LDH, beta HCG, uric acid levels are wnl.

2/3/22: Scrotal ultrasound is negative.

2/6/22- SHC admission for shortness of breath-initially relieved by 2 thoracentesis with 1-1/2 L taken out on each side. Pleural fluid confirms malignant cells, morphologically similar to mesothelioma.

2/12/-2/22/22-SHC readmission with worsening respiratory status, concern for right-sided heart failure and will remain tachycardic.
He underwent Pericardiectomy (performed by local Dr. Boyd) Bilateral PleurX catheters, Resection of mediastinal mass and thymectomy on 2/17/22
OPERATIVE FINDINGS:
1. Large bilateral chylothoraces.
2. Diffuse tumor involvement of the pericardium with areas of invasion into the myocardium

3/18/22 CT Chest- Similar to 2/26/2022, multiple pericardial masses nearly encasing the heart, thoracic lymphadenopathy, retrocrural lymphadenopathy, and adjacent right upper lobe and right middle lobe interlobular septal thickening, concerning for residual/recurrent malignancy. Interlobular septal thickening may represent lymphangitic carcinomatosis versus lymphatic obstruction. Interval increase in extensive filling defects throughout the venous system, including left internal jugular, left brachiocephalic, right internal jugular, right brachiocephalic, and right vertebral veins. No evidence of extension of the thrombus into the superior vena cava

3/18/22 - C1 Carboplatin AUC 5/Pemetrexed 375 mg/m2
Significant nausea, vomiting, fatigue- had also allergic rxn to Emend
Added low dose haldol for nausea/vomiting, compazine and reglan has not helped in past
Two admissions for symptom control

4/9/22- C2 carboplatin AUC 4, Pemetrexed 375 mg/m2 (scheduled admission for chemo given symptom burden)

4/29/22- C3 held given fatigue, cytopenia and anemia, 1 unit PRBC given

5/5/22- CT chest- Interval increased diffuse nodular interlobular septal thickening, right greater than left lung, as well as new and increasing pulmonary nodules, concerning for progression of disease.. Extensive thoracic lymphadenopathy and multiple pericardial masses nearly encasing the heart, overall stable compared to prior exam with the exception of a few lymph nodes which are slightly decreased in size.

Interval History
He is feeling okay-here for video visit with his mother.
Eating okay-although still continues to be nauseous, unpredictable if occurs with certain foods, using only Compazine as needed
He denies any current constipation
Mouth sores and pain have resolved

No chest pain or shortness of breath, fatigue persists although improved after transfusion
No blee[illegible]
Left side is draining abo[illegible] of drainage

Review of systems:
A comprehensive 14-point review of systems was performed, with pertinent positives as noted above; all other systems negative.

Past medical history:
Anxiety
Appendicitis

Past surgical history:
Past Surgical History:
Procedure Laterality Date
• BILATERAL PROCEDURE; SECONDARY MODIFIER N/A 2/17/2022
Performed by Backhus, Leah Monique, MD at STANFORD HOSPITAL 500P INTERVENTIONAL PLATFORM
• CHEST DRAINAGE CATHETER INSERTION Bilateral 2/17/2022
Performed by Backhus, Leah Monique, MD at STANFORD HOSPITAL 500P INTERVENTIONAL PLATFORM
• MEDIASTINAL LYMPHADENECTOMY, BILATERAL TUNNELED PLEURAL CATHETERS (PLEUR-X), POSSIBLE PLEURECTOMY, RADICAL PERICARDIECTOMY, THYMECTOMY WITH CPB STANDBY N/A 2/17/2022
Performed by Boyd, Jack H, MD at STANFORD HOSPITAL 500P INTERVENTIONAL PLATFORM
• THYMECTOMY; MEDIAN STERNOTOMY APPROACH N/A 2/17/2022
Performed by Backhus, Leah Monique, MD at STANFORD HOSPITAL 500P INTERVENTIONAL PLATFORM

Appendectomy 2009

Medications:
Outpatient Medications Prior to Visit
Medication Sig Dispense Refill
• acetaminophen (Tylenol 8 Hour) 650 mg TbSR take 1 Tablet by mouth daily as needed
• albuterol 90 mcg/actuation HFA inhaler 1 Puff by Inhalation route daily as needed
• cetirizine (ZyrTEC) 10 mg tablet take 1 Tablet (10 mg total) by mouth daily as needed for Allergies 30 Tablet 0
• Cholecalciferol (Vitamin D3) (Vitamin D3) 2,000 unit CAPS take 1 Capsule by mouth every day
• famotidine (Pepcid) 20 mg tablet take 1 Tablet (20 mg total) by mouth 2 times a day 180 Tablet 1
• folic acid 1 mg tablet take 1 mg by mouth daily
• gabapentin (Neurontin) 300 mg capsule take 1 Capsule (300 mg total) by mouth daily in the evening 30 Capsule 1
• HYDROmorphone (Dilaudid) 2 mg tablet take 1 Tablet (2 mg total) by mouth every 4 hours as needed (pain) 30 Tablet 0
• LORazepam (Ativan) 1 mg tablet take 1.5 Tablets (1.5 mg total) by mouth every 6 hours as needed 30 Tablet 0
• LORazepam (Ativan) 1 mg tablet take 1 Tablet (1 mg total) by mouth every 8 hours as needed 30 Tablet 0
• metoclopramide (Reglan) 10 mg tablet take 1 Tablet (10 mg total) by mouth 4 times a day as needed 30 Tablet 0
• metoclopramide (Reglan) 10 mg tablet take 10 mg by mouth 4 times a day as needed
• metoprolol succinate (Toprol XL) 25 mg extended release tablet take 3 Tablets (75 mg total) by mouth daily 90 Tablet 0
• multivitamin tablet take 1 Tablet by mouth daily 30 Tablet 0
• octreotide (SandoSTATIN) 100 mcg/mL injection inject 1 mL (100 mcg total) subcutaneous (under the skin) every 12 hours 90 Vial 0
• other drug Liocaine viscous solution 2%+Maalox+Childrens Benadryl 12.5mg/5ml (Ratio:1:1:1) -swish and spit 15 ml daily as needed
• prochlorperazine (Compazine) 10 mg tablet take 1 Tablet (10 mg total) by mouth every 6 hours as needed for Nausea/Vomiting 30 Tablet 0
• rivaroxaban (Xarelto) 20 mg tablet take 1 Tablet (20 mg total) by mouth daily with dinner After completion of loading course (15 mg BID) 90 Tablet 0
• Syringe with Needle (Disp) 1 mL 25 x 5/8" Syrg 1 Syringe by Misc.(Non-Drug; Combo Route) route every 8 hours . Use to inject octreotide (Patient taking differently: 1 Syringe by Misc.(Non-Drug; Combo Route) route every 8 hours . Use to inject octreotide) 100 Syringe 0

No facility-administered medications prior to visit.

Allergies:
NKDA

Social history: obtained at prior visits
Father works in construction and may have exposures, however only started in the past couple of years
Previously attended school in an old building, no clear asbestos exposure
Mother reports using large amounts of baby powder (Johnson and Johnson) in his childhood
No other exposures to hair salon products, chemicals in labs
Works at Home Depot
EtOH socially
No recreational drug use

Family history:

Father had ?bone cancer
Maternal [illegible] breast cancer, diagnosed [illegible] AML [illegible]

BRCA mutation:
- Mother, maternal grandmother, maternal aunts x 2

Physical Exam:
Lying down, fatigued, answering questions, + flat affect
Limited video exam

Labs and studies:
None recent- since transfusion

Imaging
As in HPI
Most recent review in tumor board of CTA 2/26/22

Pathology:
2/25/22 Pericardiectomy Specimen Review

A. THYMUS PERICARDIAL FAT
B. PERICARDIUM AND TUMOR
DIAGNOSIS (MICROSCOPIC):
A. THYMUS AND PERICARDIAL FAT, EXCISION
-- PERICARDIAL TISSUE WITH MALIGNANT MESOTHELIOMA, EPITHELIOID TYPE
-- METASTATIC MALIGNANT MESOTHELIOMA COMPLETELY REPLACING ONE LYMPH NODE (1/1)
-- EXTENSIVE VENOUS AND LYMPHATIC INVOLVEMENT BY MALIGNANT MESOTHELIOMA
-- INVOLUTED THYMIC TISSUE
B. HEART, PERICARDIUM AND TUMOR, EXCISION
-- MALIGNANT MESOTHELIOMA, EPITHELIOID TYPE
LIBERT/C. WANG/BERRY

COMMENT: We note the patient's recent diagnosis of metastatic malignant mesothelioma, epithelioid type (SHS-22-03759). The tumor present in the current resection specimen is morphologically similar.

Stanford Review
DIAGNOSIS:
LYMPH NODES. RIGHT LOWER PARATRACHEAL/4R, EXCISIONAL BIOPSY (1/10/22; 22MS-133)
-- HISTOLOGIC AND IMMUNOPHENOTYPIC FINDINGS SUPPORTING METASTATIC MALIGNANT MESOTHELIOMA, EPITHELIOID TYPE.

COMMENT: I have reviewed the H&E stained slides and accompanying immunostains and agree with Dr. Silveira as listed above. In light of the unusual diagnosis in this age group I performed a battery of immunostains in our lab along with additional H&E stained slides. The neoplastic cells within the lymph node show the following immunophenotypic profile: WT1 positive, P40 negative, CK5/6 positive, D2-40 positive, BAP1 retained, BerEP4 negative, calretinin positive, Claudin4 negative. This supports metastatic malignant mesothelioma, epithelioid type. The findings are consistent with pericardial origin.

EBUS of 4R 1/10/22:

Molecular:
2/4/22 Guardant peripheral- negative

STAMP 1/26/22

Fusion STAMP 3/15/22- Negative: No fusions detected

Assessment & Plan:
Anthony Michael Hernandez-Valdez is a 23 Y old male with newly diagnosed pericardial mesothelioma, status post

pericardiectomy and Pleurx placement on 2/17/2022, here for follow-up and 2 cycles of chemotherapy.

#Epithelioid mesothelioma, pericardium [illegible]
We had previously discussed that this appears to be a primary mesothelioma of the pericardium which is exceedingly rare, even within the rare diagnosis of mesothelioma in general. In addition him being so young and age makes this additionally difficult.
We will continue to hold chemotherapy given recent CT chest which unfortunately shows progression of disease.
-will plan to change treatment to ipilumumab/nivolumab
-send patient info- reschedule for next week
-Palliative care connection with Dr. Fronk
-Octreotide Rx sent, will message Dr. Backus and her team regarding neck steps and if drain removal would be considered on the right side

#Mouth Sores- improved- suspect chemotherapy related- reviewed using viscous lidocaine, s/ p nystatin

#Dry Skin, Linear dermatitis- possible chemo related, pending dermatology visit. I think this will be important and also is anticipating starting immunotherapy.

#Nausea- multiple medications have been tried including ondansetron, Haldol, metoclopramide, Ativan.
-Currently only using Compazine, suggested to use it at meals so every 8 hours approximately or 3 times a day.
-Appreciate Dr. Fronk's input

#Chylous Pleural Effusions- drainage decreased on right , pending input from Dr. Backhus

#Anxiety-baseline with coping of new diagnosis
Contacted Ms. Pam Simon in AYA group again
-Rx lorazepam- sent
-SW following

#Cardiac Management-in discussing the case with Dr. Boyd and Dr. Backus and reviewing the operative reports, he has still significant mesothelial tumor involvement around his heart and some into the myocardium. Recommend continuing metoprolol succinate 75 mg daily.

#Thrombosis - non occlusive thrombus bilateral internal jugular and left brachiocephalic veins-extension seen on recent CT, likely also due to impaired venous drainage from tumor burden
#Right subsegmental PE:
He is continuing on rivaroxaban daily

#Epistaxis- platelets normal, has dry skin and nares- recommended trying to moisturize nares

Acid reflux
Nausea
-increasing regimen-if contributing to nausea as well. Adding PPI- pantoprazole 40 mg and then increasing pepcid to 40

RTC scheduled for chemo cycles, repeat quest labs early next week (CBC, chem) and schedule Ipi/Nivo- first available

As usual, I encouraged the patient to contact us should he develop any new symptoms or have any questions or concerns

Mohana Roy, MD
Clinical Assistant Professor-Oncology
Stanford Cancer Center Palo Alto and South Bay

Electronically signed by Mohana Roy, MD at 05/07/2022 8:55 PM PDT

Exhibit F

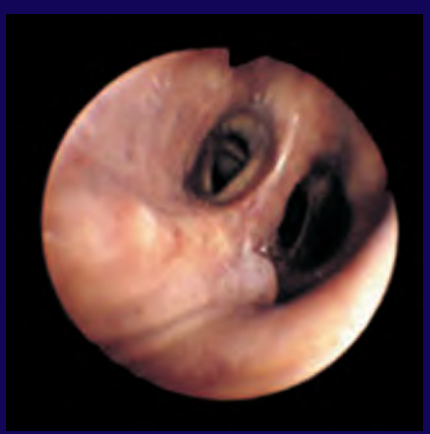
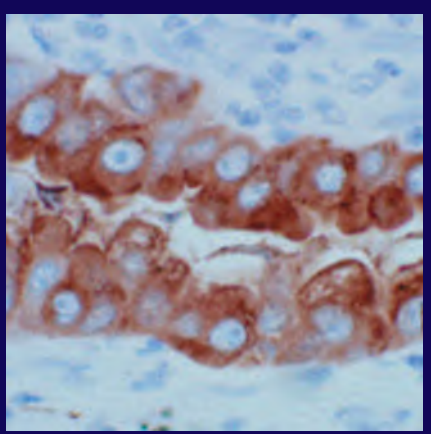
World Health Organization Classification of Tumours

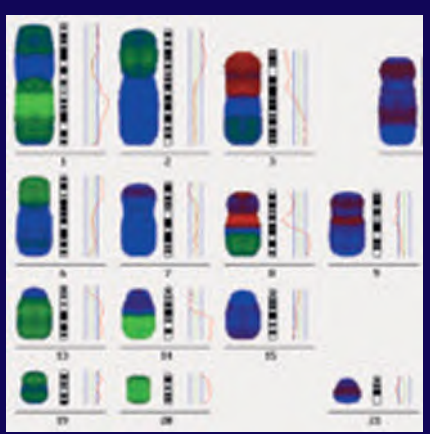
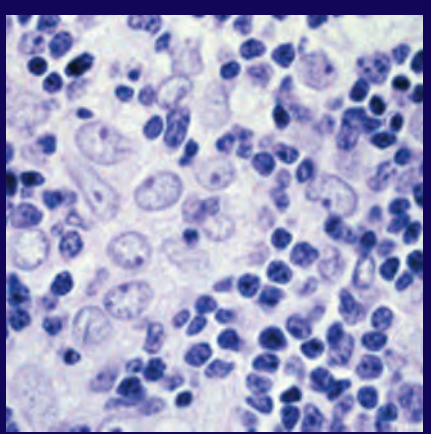
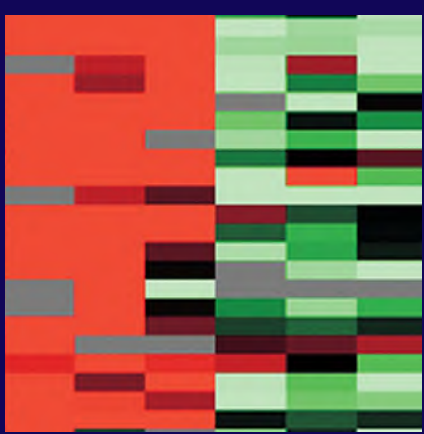
WHO Classification Tumours of the Lung, Pleura, Thymus and Heart

Pathology & Genetics

Tumours of the Lung, Pleura, Thymus and Heart

Edited by William D. Travis, Elizabeth Brambilla,
H. Konrad Müller-Hermelink and Curtis C. Harris

IARC

World Health Organization Classification of Tumours

WHO OMS

International Agency for Research on Cancer (IARC)

Pathology and Genetics of Tumours of the Lung, Pleura, Thymus and Heart

Edited by

William D. Travis
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IARC*Press*
Lyon, 2004

Pericardial tumours

A. Burke
R. Loire
R. Virmani

Solitary fibrous tumour

Definition
An uncommon, spindle-cell, fibroblastic tumour which often shows a prominent haemangiopericytoma-like vascular pattern.

ICD-O code
Solitary fibrous tumour 8815/1

Synonyms
Benign mesothelioma, fibrous mesothelioma, submesothelial fibroma

Localization
The most common locations, outside the pleura, include the head and neck, especially orbit, soft tissue, especially abdomen, extremities, and meninges {233,1384,1473}. As with any lesion common to the pleura, there have been examples of solitary fibrous tumour reported in the pericardium and rarely within the heart.

Clinical features
Clinical features are related to pericardial mass effect.

Macroscopy
Solitary fibrous tumours tend to be well-circumscribed, firm, fleshy or white although diffuse mesothelial surface involvement has been described.

Histopathology
Histologic variability is the rule and multiple growth patterns have been described. Most tumours will have a predominant monomorphic spindle cell pattern resembling low-grade fibrosarcoma although broad tumour cell fascicles are rare. Areas of hypercellularity typically alternate with those that are less cellular. The less cellular areas can by myxoid or contain abundant collagen {459}. Typically the nuclei of tumour cells are closely apposed to collagen bundles. A haemangiopericytoma-like vascular pattern may be conspicuous, present in a small portion of the lesion, or absent. The differential diagnosis includes other monomorphic spindle cell tumours, including neurogenic tumours, spindle cell mesotheliomas, monophasic synovial sarcoma, and fibrosarcoma {1311}. Recently, desmoid tumour of the pleura has been added in the list of differential diagnostic considerations {2151}. See pleural section for additional information.

Immunoprofile
Solitary fibrous tumours are CD34 and bcl-2 positive. They are consistently negative for epithelial markers, muscle specific actin, desmin, CD31, CD117 (c-kit), S-100 protein calretinin, and inhibin {596,772,1473,2127}.

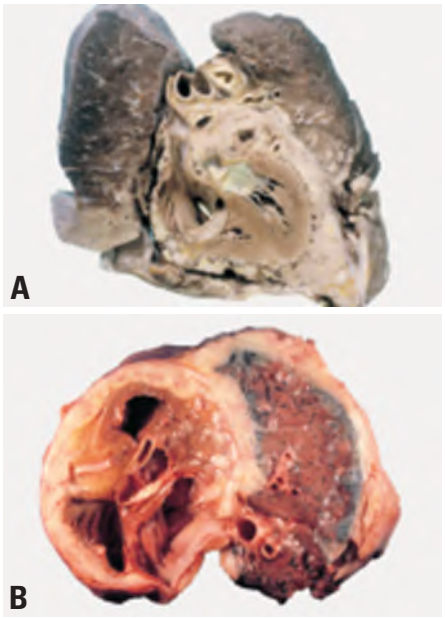

Fig. 4.39 Mesothelioma of pericardium. **A** Note the extensive tumour encasing the pericardium. **B** In many cases, the pericardial mass is in continuity with pleural mesothelioma.

Differential diagnosis
Sarcomatous mesotheliomas of the pericardium are distinguished from solitary fibrous tumours by their diffuse growth pattern, and keratin and calretinin reactivity. On the other hand, solitary fibrous tumour may closely mimic monophasic synovial sarcoma and low- grade fibrosarcoma. Fibrosarcoma tends to be more architecturally monomorphic and negative for CD34. Monophasic synovial sarcoma has higher grade cytology, plumper nuclei and shows focal keratin reactivity. Endometrial stromal sarcoma, and metastatic granulosa cell tumour may be excluded by negative reactivity for cytokeratin, estrogen and progesterone receptors, and inhibin.

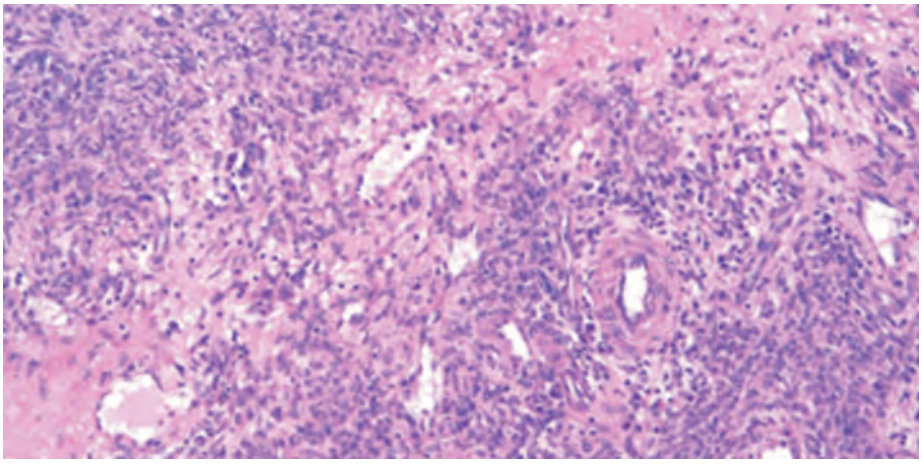

Fig. 4.40 Localized fibrous tumor of the mesothelium is identical in appearance to those of the pleura. Note the spindle cell growth with prominent vascularity and variable cellularity.

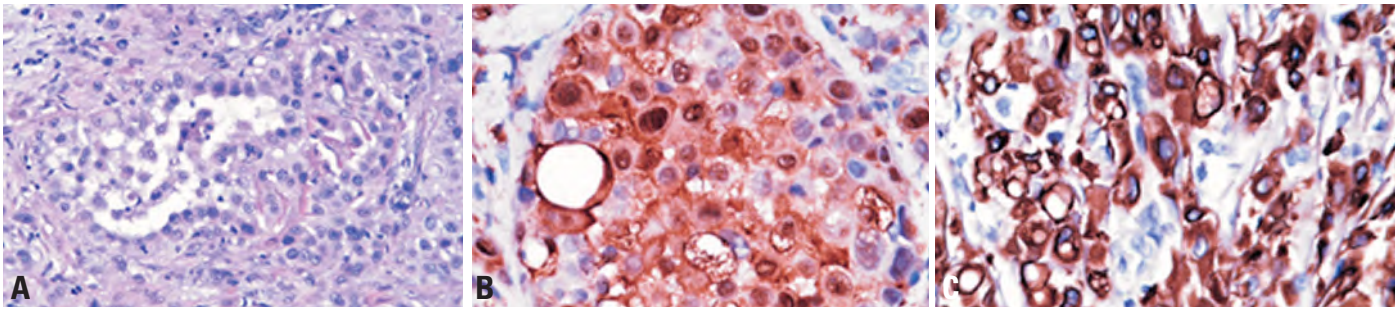

Fig. 4.41 Pericardial mesothelioma. **A** The majority of pericardial mesotheliomas are epithelioid. **B** Strong expression of calretinin. **C** Strong expression of cytokeratin 7.

Prognosis and predictive factors
The prognosis is generally good, although recurrences and local spread have been reported. Criteria for malignancy of pleural tumours include necrosis and a mitotic count of greater than 4 per 10 high powered fields, but the applicability of these criteria to tumours in the heart and pericardium is unknown.

Malignant mesothelioma

Definition
Malignant mesothelioma arises from mesothelial cells or demonstrates mesothelial differentiation. The definition of primary pericardial mesothelioma stipulates that there is no tumour present outside the pericardium, with the exception of lymph node metastases.

ICD-O code 9050/3

Epidemiology
Mesothelioma of the pericardium represents approximately 0.7% of malignant mesotheliomas {831}. As with mesotheliomas in other sites, the incidence may be increasing, due to the latency between asbestos exposure and tumour development {1074}.

Etiology
Like pleural mesotheliomas, a large proportion of mesotheliomas of the pericardium are induced by asbestos {1074}. Iatrogenically induced pericardial mesotheliomas have been reported decades after exposure to pericardial dusting with asbestos and fibreglass as a treatment for angina pectoris. Therapeutic radiation for breast cancer and mediastinal lymphoma has also been implicated in rare patients. However, there remains a subset of patients with mesothelioma who have no known exposure history.

Clinical features
Signs and symptoms
The mean age of patients with pericardial mesothelioma is about 45 years, with a wide age range, including elderly, older children and young adults. The initial course is usually related to pericardial effusions. Tamponade may eventually occur {1202}.

Imaging
Echocardiography usually shows pericardial effusions and may show pericardial thickening. However, because pericardium is at the periphery of the field of view obtainable with echocardiography, MRI or CT are usually necessary. MRI and CT usually demonstrate pericardial fluid as well as pericardial thickening and/or pericardial masses {737}.

Macroscopy
Malignant mesotheliomas of the pericardium can form bulky nodules that fill the pericardial cavity. The tumour can also spread diffusely over the pericardial surface and completely encase the heart. They can further encircle the great vessels and may obstruct the venae cavae.

Histopathology
Malignant mesotheliomas of the pericardium resemble pleural mesotheliomas. Although the majority are of the epithelioid type, forming tubules, papillary structures, and cords of infiltrating cells that can incite a desmoplastic response, the sarcomatous variant is also common. Variants similar to those described in the pleura may also be seen in the pericardium e.g. microcystic, adenomatoid, deciduoid {1649,1802}.

Immunoprofile
The immunohistochemical profile of pericardial mesothelioma is similar to that of pleural mesothelioma. Expression of mesothelial antigens, such as calretinin, and cytokeratins 5/6 are helpful in the diagnosis, as are negative reactions for adenocarcinoma markers, such as carcinoembryonic antigen.

Electron microscopy
Ultrastructurally, mesothelioma cells from epithelioid areas contain branched, bushy microvilli. Cytoplasmic tonofibrils are present in approximately 50% of tumours. Asbestos bodies may be identified within pericardial mesothelioma, but are of no diagnostic utility.

Differential diagnosis
The distinction between mesothelioma and pleural-based lung adenocarcinoma can be quite difficult, and is generally based on immunohistochemical findings. Distinction from reactive mesothelial cell proliferations may also be difficult; in comparison to reactive pleural mesothelial proliferations, reactive pericardial mesothelial cells may be more deeply “invasive”. Reactive stromal cells may also often attain bizarre and pleomorphic shapes, confusing the histopathologic picture. Other malignancies that may be confused with mesothelioma include pericardial-based angiosarcoma, which may elicit a prominent mesothelial response, malignant solitary fibrous tumour and synovial sarcoma. Immunohistochemistry is invaluable in such circumstances. Mesothelioma lacks the X;18 translocation of synovial sarcoma.

Prognosis and predictive factors
The prognosis of pericardial mesothelioma is poor. Fifty per cent of patients

Exhibit G

Received: 24 February 2020 | Revised: 5 March 2020 | Accepted: 6 March 2020

DOI: 10.1002/ajim.23106

RESEARCH ARTICLE

AMERICAN JOURNAL OF INDUSTRIAL MEDICINE WILEY

Malignant mesothelioma following repeated exposures to cosmetic talc: A case series of 75 patients

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Abstract

Background: Asbestos is the primary known cause of malignant mesothelioma. Some cosmetic talc products have been shown to contain asbestos. Recently, repeated exposures to cosmetic talc have been implicated as a cause of mesothelioma.

Methods: Seventy-five individuals (64 females; 11 males) with malignant mesothelioma, whose only known exposure to asbestos was repeated exposures to cosmetic talcum powders, were reviewed in medical-legal consultation. Out of the 75 cases, 11 were examined for asbestiform fibers.

Results: All subjects had pathologically confirmed malignant mesothelioma. The mean age at diagnosis was 61 ± 17 years. The mean latency from exposure to diagnosis was 50 ± 13 years. The mean exposure duration was 33 ± 16 years. Four mesotheliomas (5%) occurred in individuals working as barbers/cosmetologists, or in a family member who swept the barber shop. Twelve (16%) occurred in individuals less than 45 years old (10 females; 2 males). Forty-eight mesotheliomas were pleural (40 females; 8 males), 23 were peritoneal (21 females; 2 males). Two presented with concomitant pleural and peritoneal disease. There was one pericardial, and one testicular mesothelioma. The majority (51) were of the epithelioid histological subtype, followed by 13 biphasic, 8 sarcomatoid, 2 lymphohistiocytoid, and 1 poorly differentiated. Of the 11 individuals whose nontumorous tissues were analyzed for the presence of asbestiform fibers, all showed the presence of anthophyllite and/or tremolite asbestos.

Conclusions: Mesotheliomas can develop following exposures to cosmetic talcum powders. These appear to be attributable to the presence of anthophyllite and tremolite contaminants in cosmetic talcum powder.

KEYWORDS

anthophyllite, females, mesothelioma, peritoneal, pleural, talc, tremolite

1 | INTRODUCTION

Asbestos, a generic term for naturally occurring fibrous mineral silicates, is recognized as a carcinogen by the general medical and scientific communities. In 1960, Wagner et al[1] reported a large series of malignant mesotheliomas in individuals who had been exposed to asbestos from a South African asbestos mine. It has been demonstrated that all types of asbestos and even brief and low-dose exposures are capable of causing malignant mesothelioma.[2-4] In the 1970s, several types of cosmetic talcum powder products were

demonstrated to contain asbestos.[5-7] Asbestos fibers in commercial talcum powder have also been shown to become airborne upon application, and repeated exposures to cosmetic talc were implicated as a cause of mesothelioma by Gordon et al.[8] Recently, Moline et al,[9] reported a series of 33 subjects with malignant mesothelioma, whose only known exposure to asbestos was cosmetic talc. We present 75 additional subjects, with malignant mesothelioma, whose only known exposure to asbestos was cosmetic talc.

2 | METHODS

One hundred forty subjects with documented exposures to cosmetic talc were initially reviewed. Exposures were identified through sworn deposition testimonies and answers to sworn interrogatories provided from subjects, parents, and spouses. Sixty-five subjects were excluded due to recalled occupational or paraoccupational exposures to other sources of asbestos. Seventy-five subjects, whose only known exposure to asbestos was via cosmetic talc, were included for further examination. The asbestos content of talcum products and airborne asbestos concentrations during simulations of the usage of these products was determined in previously published studies.[10,11]

Tissues from biopsies and/or debulking procedures were examined and the diagnosis of malignant mesothelioma was confirmed by a board-certified pathologist (JCM, TSE, RLK). Immunohistochemical staining results for BAP-1 were available in a few cases but was not routinely performed as a part of this study.

No efforts were made to reconstruct levels of exposure but all subjects had been repeatedly exposed over many years. Eleven cases were examined for the presence of asbestiform fibers (aspect ratio, ≥3:1) in sampled tissues. Nine subjects were examined both by analytical transmission electron microscopy (ATEM) and microprobe analysis (MA) (see Table 2), whereas two were examined by scanning electron microscopy (SEM) and MA (results not shown).

3 | RESULTS

The pertinent data from the 75 subjects is shown in Table 1. All had pathologically confirmed malignant mesothelioma. Sixty-four subjects were females, 11 were males. The mean age at diagnosis was 61 ± 17 years, with a range of 14 to 94 years. The mean exposure duration was 33 ± 16 years with a range of exposure from 6 to 65 years. The mean latency from time of first exposure to diagnosis was 50 ± 13 years with a range of 14 to 72 years. A total of 4 of the 75 cases (5%) occurred in barbers/cosmetologists, or in a family member who swept the barber shop. Twelve (16%) were 45 years old or younger (10 females, 2 males) at the time of diagnosis. Forty-eight mesotheliomas were pleural (40 females; 8 in males); 23 peritoneal (21 females; 2 men). Two presented with both pleural and peritoneal disease. There was one pericardial (woman), and one testicular mesothelioma. The majority, 51 (68%) were of epithelioid subtype, 13 biphasic (17%), 8 sarcomatoid (11%), 2 lymphohistiocytoid (3%), and 1 poorly differentiated (1%). Treatment, therapeutic outcomes, and survival were not determined in this study.

For the 11 subjects whose tissues were examined by ATEM and ASEM, the analysis showed the presence of tremolite and/or anthophyllite in all 11 subjects (Table 2).

4 | DISCUSSION

The 75 individuals with malignant mesothelioma caused by asbestos in cosmetic talc is currently the largest series reported to date. Recently, Moline et al reported 33 cases of malignant mesothelioma attributed to exposures to cosmetic talc. Like Moline's work, most of mesotheliomas in the present series occurred in women. Several mesotheliomas occurred specifically in hairdressers/barbers. Similarly, the asbestos fiber types found by ATEM in the tissues examined were comparable to those found in laboratory testing for cosmetic talc.[10-12]

Mesothelioma is recognized as a "signal tumor" of asbestos exposure, that is, if a patient has mesothelioma, it should signal an inquiry into potential asbestos exposure. The presence of asbestos in talc deposits has been recognized since the late 1940s.[13,14] Since the 1960s, laboratory testing has identified asbestos in samples of cosmetic talc.[15,16] Studies have confirmed that the most common types of asbestos present in cosmetic talc are tremolite, anthophyllite, and chrysotile. Industrial asbestos products used in the United States generally contained chrysotile, amosite, and/or crocidolite,[17] and anthophyllite and tremolite were rarely present.[18]

While the latency between exposure and diagnosis in the present study is similar to the average latency for the development of mesothelioma (50 years) reported in surveillance epidemiology and end results program (SEER) data,[19] the average age at diagnosis in this report (61 years) is 11 years younger than that in the SEER data (72 years). In addition, fewer than 3% of mesotheliomas in the SEER data occurred in individuals less than 45 years of age, whereas 16% of mesotheliomas of the present study occurred in individuals less than 45 years of age, and 83% of these cases were in women.[20]

The present report of 75 cases, together with the 35 cases previously reported[8,9] currently brings the number of individuals with confirmed diagnoses of malignant mesothelioma following repeated exposure to cosmetic talcum powder to more than 100. The presence of anthophyllite and tremolite in the fiber analysis of tissues obtained from the 11 subjects in this series, is consistent with a source in cosmetic talc.

Unlike industrial or occupational exposure to asbestos, where materials have been regulated, exposure to asbestos in cosmetic talc has not been widely reported or recognized within the medical community or to the public. Cosmetic talc products are most frequently used by women in the United States, and while the incidence of mesothelioma in women is less than in men, the majority have previously been reported as "idiopathic," indicating no recognized source of asbestos exposure. The present study supports the contention that asbestos exposure through the use of cosmetic talc accounts may account for an uncertain percentage of these cases.

TABLE 1 Seventy-five mesothelioma cases exposed to talcum powder

Case	Sex	Year of diagnosis	Age at diagnosis	Mesothelioma site	Histology	Estimated years of use	Estimated years of latency
1	F	2017	72	Pleural	Epithelioid	20	57
2	F	2014	51	Peritoneal	Epithelioid	30	50
3	F	2017	50	Pleural	Lymphohistiocytoid	41	50
4	F	2017	57	Peritoneal	Epithelioid	30	52
5	F	2015	65	Pleural	Epithelioid	39	62
6	F	2017	39	Peritoneal	Sarcomatoid	15	39
7	F	2016	29	Pericardial	Epithelioid	29	29
8	F	2017	94	Pleural	Epithelioid	60	72
9	F	2015	80	Pleural	Epithelioid	19	59
10	F	2016	72	Pleural	Sarcomatoid	43	59
11	F	2013	66	Peritoneal	Epithelioid	20	52
12	F	2011	48	Pleural	Lymphohistiocytoid	13	21
13	F	2010	51	Peritoneal	Epithelioid	15	20
14	F	2018	55	Peritoneal	Epithelioid	40	42
15	M	2017	81	Pleural	Sarcomatoid	60	60
16	F	2018	56	Pleural	Epithelioid	48	52
17	F	2017	32	Peritoneal	Epithelioid	25	32
18	F	2017	89	Pleural	Sarcomatoid	40	42
19	F	2019	73	Peritoneal	Epithelioid	47	56
20	M	2016	70	Pleural	Poorly differentiated	50	55
21	F	2015	66	Pleural	Epithelioid	40	43
22	F	2016	45	Pleural	Epithelioid	10	45
23	F	2018	45	Peritoneal	Epithelioid	39	45
24	M	2015	67	Pleural + peritoneal	Epithelioid	35	60
25	M	2017	78	Peritoneal	Biphasic	50	62
26	F	2018	57	Peritoneal	Biphasic	25	57
27	F	2013	14	Peritoneal	Epithelioid	12	14
28	F	2016	67	Peritoneal	Epithelioid	15	59
29	F	2018	73	Pleural	Epithelioid	30	65
30	F	2018	76	Pleural	Biphasic	60	55
31	M	2017	39	Testis	Epithelioid	7	39
32	F	2018	57	Pleural	Sarcomatoid	57	57
33	F	2016	68	Pleural	Epithelioid	38	64
34	F	2017	80	Pleural	Epithelioid	50	60
35	F	2016	63	Pleural	Epithelioid	15	54
36	F	2017	58	Pleural	Biphasic	20	58
37	F	2017	71	Pleural	Biphasic	60	71
38	F	2014	70	Pleural	Epithelioid	41	39
39	F	2016	26	Peritoneal	Epithelioid	20	26

TABLE 1 (Continued)

Case	Sex	Year of diagnosis	Age at diagnosis	Mesothelioma site	Histology	Estimated years of use	Estimated years of latency
40	F	2016	35	Pleural	Epithelioid	35	35
41	F	2017	72	Pleural	Sarcomatoid	23	60
42	F	2016	68	Peritoneal	Epithelioid	65	68
43	F	2018	77	Pleural	Biphasic	30	55
44	M	2015	58	Plural	Biphasic	6	49
45	F	2017	72	Peritoneal	Biphasic	30	42
46	F	2017	59	Pleural + peritoneal	Epithelioid	15	44
47	F	2016	80	Pleural	Biphasic	16	52
48	M	2019	71	Pleural	Epithelioid	40	57
49	F	2017	72	Pleural	Biphasic	58	58
50	F	2017	43	Peritoneal	Epithelioid	43	43
51	F	2017	75	Peritoneal	Sarcomatoid	55	59
52	F	2015	30	Pleural	Epithelioid	20	20
53	F	2017	79	Pleural	Biphasic	65	61
54	F	2017	66	Peritoneal	Epithelioid	20	60
55	F	2015	64	Peritoneal	Epithelioid	40	40
56	F	2017	24	Pleural	Epithelioid	12	24
57	M	2017	72	Pleural	Epithelioid	30	56
58	M	2017	74	Peritoneal	Epithelioid	30	52
59	M	2015	30	Pleural	Epithelioid	20	30
60	F	2016	81	Pleural	Sarcomatoid	52	52
61	F	2017	58	Pleural	Epithelioid	58	58
62	F	2016	75	Pleural	Epithelioid	8	47
63	F	2011	88	Pleural	Epithelioid	21	71
64	F	2016	73	Peritoneal	Biphasic	41	60
65[a]	M	2017	64	Pleural	Epithelioid	18	40
66[a]	F	2014	69	Pleural	Epithelioid	16	60
67[a]	F	2014	44	Peritoneal	Epithelioid	30	39
68[a]	F	2016	68	Pleural	Epithelioid	53	52
69[a]	F	2016	72	Pleural	Epithelioid	40	51
70[a]	F	2016	67	Pleural	Epithelioid	37	53
71[a]	F	2017	58	Pleural	Epithelioid	41	46
72[a]	M	2016	44	Pleural	Epithelioid	43	44
73[a]	F	2017	51	Pleural	Epithelioid	28	49
74[a]	F	2015	47	Pleural	Epithelioid	15	40
75[a]	F	2014	62	Pleural	Biphasic	14	53

[a]Tissue analysis performed.

The present study has several limitations. It is both retrospective and uncontrolled, and the cases were submitted in medico-legal consultation, all of which potentially introduce bias. However, detailed deposition testimonies provide a level of detail concerning product exposure—including dates of exposure, duration, and frequency—that is rarely obtained in routine medical exposure histories, and which allowed for corroborating witness testimony in some cases. The strengths of the current series include its size, as malignant mesothelioma is a rare disease

TABLE 2 Fiber detection in tissue digestion from nine cases of malignant mesothelioma

Case	Mesothelioma site	Asbestos type	Tissues examined	Concentration (fibers per gram of wet tissue) Lung, lymph node, omentum, ovary	Limit of detection (fibers per gram of wet tissue) Lung, lymph node, omentum, ovary	Tissue digest weight (g) Lung, lymph node, omentum, ovary
65	Pleural	Anthophyllite, tremolite	Lung, lymph node	8625	4313	0.08, 0.34
66	Pleural	Anthophyllite	Lung, lymph node	15 333, 23 000	7667, 1150	0.06, 0.06
67	Peritoneal	Anthophyllite, tremolite	Omentum, lymph node	1917, 1725	639, 1725	0.54, 0.20
68	Pleural	Anthophyllite, tremolite	Lymph node	3044	1015	0.82, 0.34
70	Pleural	Anthophyllite, amosite, chrysotile	Lymph node	17 250	3450	1.06
71	Pleural	Anthophyllite, tremolite	Lung, lymph node	4313, 857, 3451	2156, 857, 575	0.16
72	Pleural	Anthophyllite, tremolite	Lymph node	17 250	3450	0.02
74	Pleural	Anthophyllite, tremolite	Lung	2300	460	2
75	Pleural	Anthophyllite	Lung, ovary	3450, 2070	1150, 2070	0.6, 0.2

Note: All cases shown were examined by analytical transmission electron microscopy and structures analyzed by microprobe analysis.

(1-2 cases per 100 000), and its novelty, as exposures to cosmetic talc are rarely considered by most medical practitioners when they are eliciting an exposure history to asbestos.

The findings of the present and other recent studies suggest that cosmetic talc may be a cause of malignant mesothelioma. Large-scale controlled studies will be required to assess the prospective risk of developing mesothelioma following repeated exposures to talc. Although cosmetic talcs are not currently regulated by the Food and Drug Administration, the poor prognosis of malignant mesothelioma may warrant regulation or the withdrawal of cosmetic talcs from the market, as nontoxic alternatives such as corn starch are presently available.

CONFLICTS OF INTEREST

Drs Emory, Maddox, and Kradin have testified in asbestos litigation, primarily for plaintiffs.

DISCLOSURE BY AJIM EDITOR OF RECORD

John D. Meyer declares that he has no conflict of interest in the review and publication decision regarding this article.

AUTHOR CONTRIBUTIONS

JCM and RLK developed the concept and the design of the work. JCM initiated the acquisition and developed the initial data analysis. TSE reviewed the materials, performed the statistical analysis, and was the primary author of the manuscript. RLK revised and gave the final approval of the version to be published.

ETHICS APPROVAL AND INFORMED CONSENT

As these cases were selected from medical-legal consultation practice and no identifying information was included, there was no formal institutional consent nor informed consent required.

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How to cite this article: Emory TS, Maddox JC, Kradin RL. Malignant mesothelioma following repeated exposures to cosmetic talc: A case series of 75 patients. *Am J Ind Med*. 2020;63:484–489. https://doi.org/10.1002/ajim.23106